1992

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The Postoperative Incidence of Small Bowel Obstruction Following Various Abdominal Procedures: A Six Year Retrospective Cohort Study at Yale-New Haven Hospital

A Thesis Submitted to the Yale University School of Medicine in Partial Fulfillment of the Requirements for the Degree of Doctor of Medicine

by

Ross Ian Seth Zbar

1992

ACKNOWLEDGEMENTS

It was Charles McKhann, MD whose insight and encouragement inspired this study.

It would have been impossible had it not been for William Crede, MD of the Department of Quality Assurance at Yale-New Haven Hospital. His ideas and resources were invaluable.

The assistance of Chris Hilton, computer programmer, in the Department of Clinical Information at Yale-New Haven Hospital made the gathering of data feasible.

The time given by James Jekel, MD of the Department of Epidemiology and Public Health explaining statistical analysis was much appreciated.

ABSTRACT

THE POSTOPERATIVE INCIDENCE OF SMALL BOWEL OBSTRUCTION FOLLOWING VARIOUS ABDOMINAL PROCEDURES: A SIX YEAR RETROSPECTIVE COHORT STUDY AT YALE-NEW HAVEN HOSPITAL. Ross I.S. Zbar (Sponsored by Charles F. McKhann). Department of Surgery, Yale University School of Medicine, New Haven, CT.

Postoperative adhesions are the most common cause of small bowel obstruction (SBO) in the United States. The Kaplan-Meier product-limit method was used to tabulate incidence rates of SBO in a retrospective, longitudinal cohort study of all patients at Yale-New Haven Hospital who underwent any one of nine abdominal procedures from September 30, 1985 to October 1, 1986, and who returned for follow-up during the ensuing six years. Furthermore, a descriptive analysis of all patients who underwent any one of 77 abdominal surgeries and then presented with SBO was reviewed. Analysis revealed the following incidence rates: Duhamel procedure, 66.7% obstruction during 36 months of follow-up (n=3); Colostomy, 30.8% during 69 months (n=34); Total abdominal hysterectomy, 18.2% during 70 months (n=121); Abdominoperineal resection, 14.3% during 53 months (n=9); Splenectomy, 11.2% during 65 months (n=20); Appendectomy, 10.7% during 64 months (n=41); Cholecystectomy, 6.4% during 67 months (n=141); Vaginal hystectomy, 0.0% during 70 months (n=15); and Gastroenterostomy 0.0% after 11 months (n=8). (Overall, Breslow-Cox $p < 0.00005$). An in-hospital mortality of 0.0% among obstructed patients was noted. Obstructed cancer patients (n=26) and obstructed cancer-free patients (n=32) differed in average age (62.8 years and 47.3 years, respectively, $p < 0.005$) and average total hours of surgery since entering the cohort (3.5 hours and 2.6 hours, respectively, $p < 0.0005$). Cancer patients who presented with obstruction required significantly more surgical procedures since entering the cohort ($p=0.025$), whereas differences in the total number of abdominal surgeries prior to entering the

cohort and the average duration of hospitalization for the treatment of SBO were not significant. This is the first study which utilizes Kaplan-Meier product-limit analysis to calculate specific incidences of obstruction for various abdominal operative procedures. Characterization of obstructed cancer patients and obstructed cancer-free patients demonstrated significant differences between these two groups.

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INTRODUCTION

Small bowel obstruction (SBO) is a pathological condition which causes severe morbidity and significant mortality. This condition occurs when the intestinal contents are prevented from moving along the length of the intestine. There are two categories of small bowel obstruction: mechanical and neurogenic. Mechanical SBO is due to physical occlusion, either external or internal, of the gastrointestinal lumen. A simple, mechanical obstruction occurs when only the intestinal contents are blocked; whereas a strangulated, mechanical obstruction occurs when both the intestinal contents and the intestinal blood supply are halted. Neurogenic SBO (also known as adynamic ileus) results from intestinal paralysis.

Common pathophysiologic mechanisms leading to physical obstruction of the small bowel include postoperative adhesions, internal hernia, external hernia, congenital bands, postinflammatory adhesions, inflammatory bowel disease and carcinoma. Less common causes are foreign bodies (including gallstones, parasites, fecaliths, enteroliths, concretions, bezoars, food boli and meconium), intussusception and tuberculosis. Carcinoma, diverticulitis and volvulus are major mechanisms of large bowel obstruction. Etiologic agents of neurogenic intestinal obstruction include peritoneal insult, electrolyte disturbances (especially hypokalemia), retroperitoneal hematomas, ureteral calculi, severe pyelonephritis, lower-lobe pneumonia, myocardial infarction, fractured ribs and neurological disorders (including CNS trauma and severed spinal cord).[3,11,12,15]

Although postoperative adhesions are currently the most common cause of small bowel obstruction in the United States, surprisingly few studies have specifically examined postoperative patients for subsequent small bowel obstruction. The present study applies Kaplan-Meier product-limit analysis to calculate the true, at-risk incidence of small bowel obstruction for a cohort of patients following various abdominal surgical procedures.

Additionally, a descriptive analysis of cohort patients who present with obstruction is undertaken in order to reveal any underlying characteristics within this group.

History of Intestinal Obstruction

The earliest documented case of intestinal obstruction dates from the third century BC. To treat this patient, the Greek physician Praxagoras undertook surgical intervention by:

> "[making] an incision over the [abdominal] swelling of a strangulated hernia in the inguinal area [and then] freeing the gut and cutting into the large bowel to establish an artifical anus."[49]

This ancient account does not describe how the patient recovered, or if in fact, he recovered at all. Additionally, this is an isolated account, for invasive abdominal surgery was rarely undertaken in the ancient world.

More common was the medical treatment recommended by Hippocrates, who prescribed "inflation of the rectum [with water] by means of a bladder attached to a pipe."[49] This treatment of obstruction - with enemas - continued actively until the late nineteenth century.

Generally, the ancient world considered intestinal obstruction a fatal condition. In the first century AD, the Roman medical author Celsus, wrote:

> "In ileus, it is pain which kills, along with inflammation of the bowel or straining and swelling. A most acute and most disgusting form of death...[T]hose in ileus, from excess of pain, earnestly desire death. The physician therefore, must neither be inferior to the infection nor more dilatory; but, if he finds inflammation to be the cause, open a vein at the elbow by a large orifice, so that the blood...may flow copiously...for this is...the commencement of an escape from pain."[11]

Throughout the Byzantine and Renaissance eras, the medical treatments for intestinal obstruction as outlined by Hippocrates and Celsus continued with little modification. In the sixteenth century, Ambroise Pare recommended rectal enemas and powdered wolf gut. In severe cases of obstruction, Pare was known to give bullets smeared with mercury for patients to swallow.[11] In the same century, Marianus Sanctus wrote of orally administering three pounds of mercury to a patient with obstruction and then rolling him on the ground.[49]

Noninvasive therapy for bowel obstruction generally remained unsuccessful. Woodhall, in 1639, wrote:

> "So many which are oppressed with this disease doe perish, and dies a very miserable death, ending their daies with their feyces of their owne excrements issuing out of their mouthes."[11]

In 1676, Sydenham added opium to the pharmaceutical armamentarium. The opium not only calmed the patient by decreasing the pain, but also decreased intestinal motility and occasionally helped patients recover. Sydenham felt strongly that the opium had a better therapeutic effect when administered with a live kitten on the patient's abdomen.[49] This treatment was to remain popular for two centuries.

The late seventeenth century also marked the beginning of abdominal paracentesis. This treatment, although considered dangerous, was used as a last resort in all types of abdominal distension, including obstruction.[11] This method of treatment lasted for two hundred years, for Blake and Bigelow reported using percutaneous intestinal puncture for the treatment of intestinal obstruction in Boston as late as 1876.[49]

There were scattered reports of the surgical treatment of bowel obstruction during the late Renaissance and Enlightenment periods. In 1561, Franco operated on a strangulated hernia by making an incision over the swelling and cutting the constricting band.[49]

Bonetus described the successful reduction of an intussusception through surgical management in 1679.[11] With the founding of the French Royal Academy of Surgery in 1731 by La Peyronie and Mareschal, the exchange and study of surgical techniques involving the bowel became popular. One surgeon reported that he excised gangrenous bowel and created an artifical anus in a woman with a strangulated hernia as early as 1701. La Peyronie stated that he opened the peritoneal cavity to treat a case of intestinal obstruction. In 1740, Pipelet reported the excision of several inches of dead bowel and the creation of an artificial anus to treat an incarcerated hernia.[49] Pillore of Rouen performed the first intraperitoneal cecostomy with a rubber enema pipe in 1776 to relieve obstruction.[11] Yet despite these well documented case reports, the surgical treatment of intestinal obstruction did not make a lasting impression upon surgeons outside of France. Furthermore, with the French revolution, the Royal Academy was dissolved.

For some time, electrical stimulation became the popular treatment. This involved completing an electrical circuit between the patient's rectum and the abdominal wall as reported by L'Etoille in 1826.[49] Forty years later, Kussmaul suggested the use of gastric lavage to wash out the "intestinal toxins."[49] Nevertheless, despite all of these treatments, intestinal obstruction remained highly fatal. In the 1880s, Furbringer wrote:

> "The medical management of intestinal obstruction is not so bad, nor the results of surgery not so good, as to warrant calling in the surgeon."[49]

However, it was Frederick Treves of London Hospital in 1899 who began promoting the modern surgical management of bowel obstruction. Treves wrote: "It is less dangerous to leap from the Clifton Suspension Bridge than suffer from acute intestinal obstruction and decline operation."[49] Although his viewpoint was initially met with resistance, physicians slowly adopted a surgical approach to obstruction at the turn of the century.

With the development of the gastroduodenal tube in the early twentieth century, a new era dawned in the treatment of intestinal obstruction. The intestinal tube was developed from the already existing stomach tube. The first use of a stomach tube was recorded by Hunter in 1790 to treat a patient with achalasia. This tube was made of eelskin.[50] Then in 1910, Gross and Eihorn developed nasogastric tubes with weighted metal tips. The Levin nasogastric tube was a 1921 development, which lacked the metal tip. However, it was Wangensteen who in 1931 applied suction to an indwelling intestinal tube and decompressed three acute intestinal obstructions. Wangensteen's intestinal tube underwent several modifications. In the late 1930s, Miller and Abbott made a double lumen, rubber tube with an air filled balloon tip. Johnston designed an intestinal tube with a larger lumen and Dennis created a tube with three lumens. In 1946, Cantor introduced a single lumen tube with a greater inner diameter and with more holes in the tip. Additionally, the tip was loaded down with a mercury filled balloon.[50] Although Wangensteen recognized the need for early operative intervention in patients with either intestinal strangulation or failed intestinal tube therapy, the long tube was abused in the late 1940s with many patients developing perforation or gangrenous bowel.[9] By the end of the 1950s, however, the appropriate indications for conservative intestinal tube therapy became well defined. These indications are discussed later.

Changing Etiology of Intestinal Obstruction

Careful review of studies reported over the last century demonstrates a changing etiology of intestinal obstruction in the Western World. As surgical attitudes have changed about entering the abdomen, so have the nature of intestinal obstructions.

Table I lists many of the major studies conducted during the past 100 years concerning intestinal obstruction and its etiology. An interesting trend emerges: The percent of obstructions caused by hernias has decreased, while the percent of obstructions caused by

postoperative adhesions has increased. This is due to both the earlier repair of hernias by Western surgeons, as well as, an increase in the number of abdominal procedures performed which generate postoperative adhesions.[6]

The presence of adhesive bands in patients with bowel obstruction, even in the absence of previous surgery, is demonstrated in several studies.[11,12,38,39] The percent of obstructions caused by these adhesions in nonsurgical patients varies, but is generally between 5% to 15%.[11] Such bands are congenital or secondary to previous episodes of inflammation.

Of further interest is the current etiology of intestinal obstruction in developing countries, which is similar to that of England and the United States at the turn of the century. Chakrabarty illustrated this in his study from India, conducted from 1968 through 1974, which revealed strangulated external hernia to be the most common etiology of intestinal obstruction.[12] This finding was due to both the higher rate of untreated hernias which were allowed to progress to strangulation or obstruction, as well as, the lower rate of laparotomy in developing countries.

Nevertheless, today, postoperative adhesions are the most common cause of bowel obstruction in the United States.

Postoperative Adhesion Formation

The underlying pathophysiology of postoperative adhesion formation is not well understood. In 1843, Samuel Gross was the first to make the experimental observation of adhesion genesis. He noted that after suturing intestinal wounds in dogs, there followed an attachment of omentum to the surface and edges of the wound.[15] In the early twentieth century, adhesions in postoperative patients were observed to form between bowel, incision, abdominal wall and drain site. Adhesions were also commonly present after

sepsis, anastomotic leak or peritonitis. The structure most commonly involved was the omentum, followed by the ileum and the jejunum.[50]

From the above observations, surgeons felt that mechanical trauma to the intestine was the sole component necessary for adhesion genesis. A 1935 textbook described the adhesion process as:

> "hyperemia and edema of inflamed serosa, [followed by] rapid deposition of fibrin. Involved surfaces [then] adhere together. This fibrous network may absorb within a few days. In other cases organization may occur with the growth of blood vessels and fibroblasts [and] development of fibrous adhesions."[15]

Although the histiological description is accurate, surgeons incorrectly assumed that fibrin deposition would occur only if the serosal vascular network was not intact, therefore preventing reabsorption of fibrous exudate. Damage of the vascular network - through mechanical trauma, retraction, surgical denudement - was equated with adhesion formation.

This proved to be only part of the answer, for in 1955, Williams demonstrated that abrasion of the parietal peritoneum in rabbits did not necessarily lead to adhesions.[51] A similar experiment was performed by Dembowski in 1888, but unfortunately, it had been largely ignored.[15] However, it was Ellis who finally accounted for these observations by proposing the ischemic vascular model of adhesion formation. This model postulated that vascular in-growth occurs toward ischemic peritoneal tissues. Then, with the ischemic crisis over, the vascular collateral channels reabsorb and leave a fibrous matrix.[16] Thus the fibrous adhesions represent "vascular grafts" to ischemic areas in the peritoneal cavity. Ellis successfully supported his hypothesis by tying off mesenteric arteries in controlled experiments with rats.[16] Also of note is the work of Belzer, who demonstrated that venous congestion, with intact lymphatic flow, promoted extensive adhesion formation.[2]

Buckman showed that deperitonealized tissue has a high fibrinolytic activity which ischemic tissue lacks.[10] Thus reperitonealizing the abdomen with sutured peritoneum, which is itself ischemic, in fact promotes adhesion formation.

Other factors associated with adhesion formation include foreign body granulomas. In particular, talc (magnesium silicate), which was formerly used as a surgical glove lubricant, produces a severe foreign body reaction and granuloma formation.[31] Gauze lint, suture filament and anti-microbial solutions have also been implicated in the formation of granulomas which promote adhesions.[50] Although the current surgical glove lubricant, starch, is absorbed within four weeks and supposedly does not produce foreign body reactions, there have been reported cases of large, intra-abdominal starch particles promoting granulomas.[50]

Chemical irritation of the peritoneum is associated with adhesion formation. This includes peritoneal infection, whether localized or generalized, pooled blood and spillage of gastrointestinal tract contents.[31]

Thermal injury is another avenue for adhesion formation. There is evidence that laparotomy pads, which are either too hot or too cold, can generate enough tissue damage to promote adhesion formation.[31]

The actual connection between adhesion formation and intestinal obstruction is straightforward. By tacking the bowel in place, the adhesions can promote bowel to kink or wrap. Additionally, adhesions can form constricting bands which contract with time.

Surgeons have tried experimentally to limit adhesion formation, despite the many different mechanisms involved. Attempts to remove fibrin exudate with proteolytic enzymes, prevent fibrin deposition with anticoagulants, or inhibit fibroblastic proliferation with steroids and antihistamines have not met with any great success.[50]

Measures which are recommended to decrease the likelihood of postoperative adhesion formation, but certainly not prevent it, include: washing off glove powder; local and systemic treatment of abdominal infection; removing all foreign matter; using warm, moist

laparotomy pads to pack bowel; nonclosure of raw peritoneal surfaces; eliminating long, multifilament sutures and their tails; avoiding mass ligatures; achieving complete hemostasis; and using gentle surgical technique.[50]

Symptoms of Small Bowel Obstruction

The symptoms of simple, non-strangulated, small bowel obstruction include episodic and colicky pain, nausea, vomiting and obstipation. Physical exam may be remarkable for hyperactive, high-pitched bowel sounds, abdominal distention or mass. However, it is the abdominal x-ray findings of dilated loops of small bowel with air-fluid levels that is the *sine qua non* of small bowel obstruction.[27]

Many studies have documented that there is absolutely no correlation between either temperature, pulse, abdominal wall rigidity, pain, white blood cell count, degree of nausea or vomiting with the diagnosis of non-strangulated, small bowel obstruction.[6,27,36,37] Additionally, the duration of obstructive symptoms prior to hospitalization does not correlate with the likelihood of strangulation.[6]

Pathophysiology of Small Bowel Obstruction

In simple, non-strangulated small bowel obstruction, distension of the bowel wall begins immediately, although it may not become clinically evident for some time. The distension is due to the absence of peristalsis and the resulting accumulation of ingested material in the gut lumen. This causes additional decreases in normal intestinal absorption and increases in fluid secretion from the intestinal mucosa secondary to osmotic forces. An increase in trapped, swallowed air also plays a key role in distension of bowel wall.[3]

Early distension is not itself directly life threatening; however, the sequelae are harmful. These include discomfort, increased difficulty with respiration and sequestration of large volumes of fluid within the bowel lumen.

If the obstruction remains unrelieved, the small bowel will continue to distend until the pressure within the bowel wall is equal to (or greater than) the local venous pressure. This increase in venous pressure results in greater intestinal capillary permeability with even further distension of bowel wall. When the intraluminal pressure of obstructed bowel equals the local arterial pressure, oxygenated blood is prevented from reaching the segment of obstructed bowel, causing strangulation. The strangulated bowel segment is more likely to leak its bacterial laden contents, first microscopically through bacterial translocation and then grossly, causing generalized abdominal sepsis. This strangulated segment of bowel is also more likely to become completely gangrenous. Frank perforation of the bowel wall may also occur, resulting in severe sepsis.

Early versus Delayed Small Bowel Obstruction

Two types of mechanical, postoperative small bowel obstructions are recognized by surgeons: early and delayed. Although various definitions of early postoperative SBO have been used, it is generally agreed to occur up to four weeks after an abdominal operation. Delayed postoperative SBO can occur any time after 30 days from an abdominal operation.

However, the diagnosis of early postoperative SBO is not always easy. This is due to the difficulty differentiating clinically between postoperative paralytic ileus and early postoperative obstruction. In the early postoperative period, some of the symptoms of SBO are in fact normal sequelae of abdominal surgery and paralytic ileus, especially abdominal pain, nausea, distension and lack of flatus.

Despite this difficulty in clinical differentiation, most studies of early postoperative SBO examine all patients who are within 30 days of abdominal operation, including those who

are still in the hospital and have never fully recovered gastrointestinal function or who are being concomitantly treated for other medical problems.[13,18,30,36,37,46] In order to eliminate this potential bias (*i.e.* - incorrectly reporting postoperative ileus as early SBO), a universally accepted definition of early postoperative small bowel obstruction should be agreed upon. For the purposes of this study, and in an attempt to eliminate potential bias, early postoperative SBO was defined as an obstructive event occurring in patients who were discharged from the hospital with a functioning intestine after an abdominal procedure, but were then re-admitted with SBO within 30 days of that same procedure.

Previous Studies of Small Bowel Obstruction After Abdominal Surgery

Previous studies have examined both early and delayed small bowel obstruction secondary to postoperative adhesions, but few have accurately explored the true, at-risk incidence of SBO following various abdominal procedures.[4,14,22,25,32,34,35,36,48] These earlier studies only reported the percentages of obstructed patients who each had a different type of abdominal surgery. Statistically speaking, this is highly deceptive because these numbers represent only a proportion of procedures performed among postoperative patients with SBO, not an incidence rate of SBO. Furthermore, these percentages only represent the relative frequency of operative procedures in a particular region at a particular time in these obstructed patients.[17]

For example, finding that 40% of patients with postoperative small bowel obstruction had previous gynecological surgery allows one to only say, statistically, that in a particular place at a particular point in time, 40% of the patients presenting with postoperative SBO had previous gynecological surgery. From these data, there are no statistically sound methods to calculate an incidence rate of small bowel obstruction over time among patients who underwent gynecological surgery. However, if there were a cohort of patients receiving gynecological surgery followed over time, a statistically significant incidence rate

of small bowel obstruction could be calculated using the Kaplan-Meier product-limit method, as discussed later.

Previous Attempts to Derive an Incidence of Small Bowel Obstruction

Over the past several decades, several studies have attempted to calculate an incidence rate for small bowel obstruction. McEntee reported an incidence of 39.9 cases of small bowel obstruction per 100,000 population per year.[28] This number is a *heterodemic* ratio, which was calculated by including all those patients with an event in the numerator and using the size of the regional population in the denominator. *Heterodemic* ratios are used in many epidemiological studies; however, this approach is inadequate for calculating a postoperative incidence value of obstruction which is of use for a surgeon, for all the people in the denominator are not necessarily accounted for in the numerator.[17] Thus not all the people in the denominator are necessarily at risk for obstruction nor do they receive any type of follow-up. Additionally, the denominator is obtained from regional census figures which may be inaccurate. The *heterodemic* incidence figure is not useful when searching for an incidence rate of a specific event in a specific population.

Lewis' study of appendicitis,[26] has been used to calculate the incidence of small bowel obstruction following appendectomy.[50] However, review of the original work demonstrated that the quoted incidence of 0.2% represents only early postoperative small bowel obstruction in patients who had not been discharged from the hospital.[26] There was no follow-up in this study whatsoever.

Melody came fairly close to calculating a statistically sound incidence rate for small bowel obstruction following total abdominal hysterectomy. He reported a 2.8% incidence rate of SBO among his personal series of 210 patients.[29] This incidence rate was calculated by taking the total number of patients who received follow-up and dividing by the total number of patients who subsequently developed small bowel obstruction.

Unfortunately, the author failed to report how he obtained follow-up data and how he accounted for varying duration of follow-up. Thus not all 210 patients at risk in the denominator, may actually be accounted for in the numerator. Also, Melody failed to clearly differentiate between early and delayed postoperative small bowel obstruction.

Sannella's calculation of postoperative small bowel obstruction following abdominoperineal resection seems statistically sound, although he omitted vital descriptions of his statistical methodology.[42] He reported an overall incidence of small bowel obstruction following APR of 10.8%. Additionally, he differentiated between early and delayed small bowel obstruction. Sannella's study would have been stronger had he described the exact methodology of incorporating the follow-up data. How did he account for different duration of follow-up? How were patients lost to follow-up handled? Because of these shortcomings, the incidence value cannot be considered statistically reliable.

Purpose of the Present Study

Since postoperative adhesions are the most common cause of small bowel obstruction in developed nations, it is important to specifically examine patients with this pathology. Moreover, with the advent of laparoscopic abdominal surgery, an in-depth study of postoperative adhesions is highly desirable to establish baseline statistics from the pre-laparoscopy era. Also, with the increasing number of elective abdominal procedures in a litigious society, concern about postoperative adhesions may increase. This study will seek to answer several questions: What is the six year incidence of small bowel obstruction secondary to postoperative adhesions following selected abdominal procedures? Are some abdominal procedures more apt to cause adhesion formation and subsequent small bowel obstruction than others? What is the morbidity and mortality of the postoperative patient

presenting with small bowel obstruction? What is the impact of the primary pathology in obstructed patients?

Design of the Present Study

In order to accurately obtain information concerning SBO after abdominal surgery, a longitudinal cohort study must be performed.[17] That is to say, a group of patients who underwent a specific abdominal procedure must be followed forward in time and observed for development of obstruction.

Ideally, to find the statistically correct incidence of small bowel obstruction during a specific duration of time, a ratio may be set up. In this ratio, the numerator includes all the cohort patients with small bowel obstruction (*i.e.* - an event) and the denominator contains all the cohort patients at risk for obstruction during a certain amount of time of observation. However, since these cohort patients are actually each observed for various amounts of time and are lost to follow-up at different points in time, both the numerator and denominator must be appropriately adjusted, for final outcomes of lost patients are unknown.

The Kaplan-Meier product-limit life table analysis adjusts the incidence ratio to account for the various durations of follow-up and the losses to follow-up experienced within the observed cohort.[24] This method of analysis calculates the cumulative proportion of surviving patients relative to the individual survival time for each patient. Therefore, data from a patient who was lost to follow-up after 15 months may still be used with data from a patient lost to follow-up after 65 months, because the Kaplan-Meier product-limit tallies each patient at risk for an event in the denominator until he or she suffers an event or is lost to follow-up. Therefore, Kaplan-Meier product-limit analysis accurately tabulates an adjusted probability curve, with respect to duration of follow-up, for an obstructing event in all patients from the observed cohort over time. Additionally, the Kaplan-Meier product-

limit calculates accurate incidence rates for small cohorts (n<10), assuming the observed cohort is not subject to sample size bias (*i.e.* - the small cohort contains patients who are in fact representative of the underlying population).

Two assumptions are made by the Kaplan-Meier product-limit analysis. These are: (1) that patients lost to follow-up have a similar fate as those who remain in the study; and (2) that the time period in which a patient is enrolled in the study has no independent effect on the outcome. Both of these assumptions, as they pertain to the present study, are discussed later.

This study design is particularly powerful in that it is *homodemic*, meaning each patient in the cohort who is at risk for small bowel obstruction and thus represented in the denominator, is accounted for in the numerator through the use of follow-up data.[17] This *homodemic* design eliminates any speculation about patient outcome following surgery because each patient who is at risk for small bowel obstruction is followed over time for an event.

Using the Kaplan-Meier product-limit analysis, it is not significant whether this study is carried out in a retrospective or prospective fashion. This is because the study design is *homodemic* and each cohort patient receives individual follow-up. Obviously, the retrospective design allows for rapid data assessment. Potential for recall bias is eliminated because only complete medical records are reviewed.

In the present study, the abdominal procedures selected for Kaplan-Meier product-limit analysis for subsequent SBO include colostomy, appendectomy, cholecystectomy and splenectomy; all of which are among the most common surgeries performed today. Total abdominal hysterectomy, by far the most frequent gynecological operation, and vaginal hysterectomy are also subjected to Kaplan-Meier product-limit analysis for postoperative small bowel obstruction. Moreover, two uncommon operations, Duhamel procedure and gastroenterostomy, are included. Abdominoperineal resection is the only procedure examined in the present study which is indicated solely for rectal cancer.

The Duhamel procedure is one of several surgical options which may be used for the treatment of Hirschsprung's disease in children (congenital aganglionic megacolon). It is a two-staged procedure: An initial colostomy is later followed by a retrorectal pull-through procedure which perserves a partially aganglionic rectum. Recognized complications include progressive constipation and obstipation secondary to anterior pouch formation, fecal impaction and colonic spurs.[41]

Therefore, the present study represents the first application of Kaplan-Meier product-limit analysis to generate incidence rates for postoperative small bowel obstruction following selected abdominal procedures. Additionally, a descriptive analysis of the postoperative cohort with small bowel obstruction will allow comparison with previous studies.

MATERIALS AND METHODS

Cohort Parameters

A surgical cohort of patients at Yale-New Haven Hospital was created which included all those patients who underwent any one of the 86 specified, primary abdominal procedures listed in Table II during fiscal year 1986 (September 30, 1985 through October 1, 1986) and who were then discharged alive from the hospital. These patients were identified through a computer search of a data base in the Department of Quality Assurance at Yale-New Haven Hospital which recorded all operative procedures according to the International Classification of Diseases - Ninth Revision (ICD-9)[23] code since fiscal year 1986. All of those cohort patients who returned to Yale-New Haven Hospital with a subsequent admitting diagnosis code of small bowel obstruction from fiscal year 1986 through fiscal year 1991 (September 30, 1985 through October 1, 1991) were then identified by an additional computer search of admitting ICD-9 codes. The complete medical records of cohort patients with small bowel obstruction were then manually reviewed.

The admitting diagnosis of small bowel obstruction was based upon a combination of history (pain, nausea, vomiting, obstipation), physical exam (bowel sounds, abdominal distention, mass) and abdominal x-ray findings (dilated loops of small bowel, air-fluid levels). Not every patient had all of the criteria for small bowel obstruction; however, all patients had sufficient radiologic evidence of small bowel obstruction in combination with a significant number of history and physical exam findings. Patients without a discharge diagnosis of SBO were excluded from the study.

Patients with small bowel obstruction secondary to incarcerated hernia or mesenteric vascular disease were not included in this study. Furthermore, patients from the initial

surgical cohort who developed small bowel obstruction at Yale-New Haven Hospital during a subsequent hospitalization for an admitting diagnosis other than SBO, were omitted from this study in order to eliminate possible bias in diagnosis and treatment of obstruction with concomitant, underlying disease. Patients from the cohort who were transferred from other hospitals with small bowel obstruction were also excluded to eliminate the bias of an outside work-up and partial treatment. Patients with the admitting diagnoses of partial small bowel obstruction, intermittent small bowel obstruction, pseudo-obstruction (Ogilvie's syndrome), large bowel obstruction, fecal impaction, paralytic ileus or abdominal pain were eliminated from the study. No patients were rejected from this study on the basis of age or sex. Any patient with an incomplete medical record was disqualified.

Information garnered from the medical records included: birth date; sex; race; any history of abdominal surgery prior to entering the cohort; date of abdominal procedure indexing the patient as a member of the surgical cohort; type of indexing abdominal procedure performed; indication for indexing procedure; length of procedure; wound classification; dates of subsequent abdominal procedures; types of subsequent abdominal procedures; length of subsequent procedures; wound classifications of subsequent procedures; date of first small bowel obstruction; type of medical and/or surgical treatment for small bowel obstruction; duration of medical and/or surgical treatment for small bowel obstruction; evidence of cancer recurrence, if applicable; number of subsequent small bowel obstructions and treatment.

Cohort patients who returned to Yale-New Haven Hospital with an admitting diagnosis of small bowel obstruction within 30 days of their most recent abdominal procedure were defined as having early mechanical SBO.

Cohort patients were identified as cancer patients if the indication for their index abdominal procedure was treatment of cancer or if subsequent development of cancer required abdominal surgery. Patients receiving palliative procedures for cancer were

excluded from this study. Information regarding cancer histology and any history of radiation therapy directed towards the abdomen was obtained from the medical records of cancer patients. Patients who were identified as having cancer and who returned to Yale-New Haven Hospital with small bowel obstruction, were classified as having obstruction secondary to adhesions (*i.e.* - cancer-free), only if at surgery to treat obstruction there was either no evidence of cancer recurrence, or the episode of obstruction resolved in fewer than five days of medical therapy and there was no evidence of cancer recurrence in subsequent medical records. Otherwise, cohort patients with cancer who returned to Yale-New Haven Hospital with small bowel obstruction had their postoperative obstruction classified as secondary to cancer.

Statistical Analysis

Statistical significance testing was performed appropriately with either the two-sample t test for independent samples with equal variances, two-sample t test for independent samples with unequal variances (Cochran's Method), Yates corrected chi-square test for a 2 x 2 contingency table, Fisher's exact test, and chi-square test for an R x C contingency table.[40]

Life table analysis was performed using the Kaplan-Meier product-limit method[24] as calculated by BioMedical Data Processing Software. The Kaplan-Meier product-limit calculates incidence curves over time by using follow-up data from all individuals in the cohort, regardless of duration of follow-up. This is accomplished by first numerically ranking all the patients in the cohort according to the increasing duration of their follow-up (*i.e.* - number of months observed without an event) and noting their outcome (i.e. - obstruction or loss to follow-up). The Kaplan-Meier product-limit method tabulates the probability of an event over a certain length of time, t_x by taking the product of the cumulative proportion of cohort patients surviving a certain time increment, t_1, without an

event and multiplying by the proportion of cohort patients surviving without an event in the current time period.[24] Therefore, if the cohort size is n, and rank of the cohort patient without small bowel obstruction relative to the duration of follow-up is r, the proportion of patients surviving the time increment, t_1, without an event is $[(n-r)/(n-r+1)]_{t1}$. Thus the total probability of an event occurring over a time period, $Pr[E(t)]$, is the product of the various proportions surviving without an event up to that current point in time, t_x. This may be expressed as:

$$Pr[E(t)] = [(n-r)/(n-r+1)]_{t1} * [(n-r)/(n-r+1)]_{t2} * [(n-r)/(n-r+1)]_{t3} *...[(n-r)/(n-r+1)]_{tx}$$

The Kaplan-Meier product-limit was calculated for the following indexing abdominal procedures: appendectomy, cholecystectomy, splenectomy, colostomy, total abdominal hysterectomy, vaginal hysterectomy, abdominoperineal resection, Duhamel pull-through, and gastroenterostomy. Statistical comparison of Kaplan-Meier incidence curves over time was performed approproately using the Breslow-Cox test of significance.

Follow-Up Data

Patient follow-up data for the Kaplan-Meier life table was obtained by tracking each patient in the surgical cohort through the use of computerized admitting diagnosis codes in the Department of Quality Assurance, from fiscal year 1986 through fiscal year 1991, and noting when, if at all, the patient was readmitted to Yale-New Haven Hospital. Patients who came back to Yale-New Haven Hospital with any subsequent diagnosis or procedure were considered to be Yale-New Haven Hospital users, up until their most recent admission date (*i.e.* - no interval hospitalization elsewhere). This date was used to

calculate the duration of follow-up. Those patients who never returned to Yale-New Haven Hospital after the index abdominal procedure were considered lost to follow-up.

Incidence Density

The incidence density for various abdominal procedures was calculated by dividing the number of small bowel obstructions for a specific procedure by the total number of patient-months of follow-up for that specific procedure and then multiplying the quotient by 1000. The result was expressed as the number of SBOs per 1000 patient-months of follow-up. The incidence density accounts for the three-dimensionality of the data, and profiles the cohort, by producing a ratio of the total number of events to the total amount of follow-up in the cohort for each abdominal procedure.

Technical Assistance

All computer programs accessing data from the Yale-New Haven Hospital data base were designed in consultation with the Department of Quality Assurance at Yale-New Haven Hospital. Program entry was performed by Chris Hilton of the Department of Clinical Information. Otherwise, all work was performed by the author.

RESULTS

Of the 3,810 patients in the postoperative cohort, 58 (1.5%) returned to Yale-New Haven Hospital with an admitting diagnosis of small bowel obstruction. Of these 58 postoperative patients returning with small bowel obstruction, seven (12.1%) had early SBO and 51 (87.9%) had delayed SBO. Moreover, a total of 27 patients (46.6%) required operation to relieve obstruction. Twenty-six patients (44.8%) had SBO secondary to recurrent cancer, of which seven (26.9%) required surgical intervention.

Kaplan-Meier Product-Limit Analysis

Figure I shows the survivorship curves as calculated from the Kaplan-Meier product-limit for the following procedures: appendectomy, colostomy, total abdominal hysterectomy (TAH), vaginal hysterectomy, cholecystectomy, splenectomy, gastroenterostomy, Duhamel pull-through procedure and abdominoperineal resection (APR). These curves graph the proportion of patients who survived their follow-up time without small bowel obstruction.

Table III displays information concerning the total numbers of each procedure performed, the total number of patients who returned for follow-up after each procedure, the total duration of follow-up for each procedure, the total number of patients receiving follow-up who subsequently developed SBO after each procedure, the adjusted Kaplan-Meier incidence rate of obstruction and the incidence density for each procedure. Both Figure I and Table III will be discussed together in greater detail.

Appendectomy

The cohort of patients receiving follow-up after appendectomy consisted of 41 persons. Of these, three (7.3%) had small bowel obstruction during 64 months of follow-up,

resulting in an adjusted Kaplan-Meier incidence rate of 10.7%. The incidence density for appendectomy was 2.2 SBOs per 1000 patient-months of follow-up. Of the three patients who developed SBO after appendectomy, two (66.7%) had perforated appendices at the time of the index procedure.

Colostomy

There were 34 patients who received follow-up after colostomy. Of these patients, seven (20.6%) developed small bowel obstruction during 69 months of follow-up, resulting in an adjusted Kaplan-Meier incidence rate of 30.8%. The incidence density for colostomy was 8.3 SBOs per 1000 patient-months of follow-up. Five (71.4%) of the patients returning with obstruction from this group underwent their initial colostomy for cancer.

Total Abdominal Hysterectomy

There were 121 patients in the cohort who received follow-up after total abdominal hysterectomy. Of these women, 14 (11.6%) developed small bowel obstruction during 70 months of follow-up, resulting in an adjusted Kaplan-Meier incidence rate of 18.2%. The incidence density for TAH was 4.1 SBOs per 1000 patient-months of follow-up. Eight (57.1%) of the women who presented with obstruction had their TAH for cancer.

Cholecystectomy

There were 141 patients who received follow-up after cholecystectomy. In this cohort, three (2.1%) of the patients developed small bowel obstruction during 67 months of follow-up, resulting in an adjusted Kaplan-Meier incidence rate of 6.4%. The incidence density for SBO after cholecystectomy was 0.7 SBOs per 1000 patient-months of follow-up. Of the three patients who had SBO following cholecystectomy, one (33.3%) had a perforated gallbladder at the time of index procedure.

Splenectomy

Twenty patients had follow-up after splenectomy. From this group, two (10%) developed small bowel obstruction during 65 months of follow-up, resulting in an adjusted

Kaplan-Meier incidence rate of 11.2%. The incidence density for splenectomy was 4.1 SBOs per 1000 patient-months of follow-up. All the obstructions occurred within the first seven months of follow-up. None of these patients had splenectomy for cancer or for cancer-related staging.

Abdominoperineal Resection

There were nine patients who returned for follow-up after abdominoperineal resection. From this group, one (11.1%) of the patients developed small bowel obstruction during 53 months of follow-up, resulting in an adjusted Kaplan-Meier incidence rate of 14.3%. The incidence density for APR was 4.0 SBOs per 1000 patient-months of follow-up.

Vaginal Hysterectomy / Gastroenterostomy

No patients returned to Yale-New Haven Hospital with small bowel obstruction who underwent either vaginal hysterectomy or gastroenterostomy. The vaginal hysterectomy cohort was followed for 70 months and the gastroenterostomy cohort was followed for 11 months. The size of these cohorts was 15 and 8 respectively. The incidence density was zero for both procedures.

Duhamel Procedure

There were three patients who received follow-up after Duhamel pull-through procedure. Two (66.7%) of these patients developed small bowel obstruction during 36 months of follow-up, resulting in an adjusted Kaplan-Meier incidence rate of 66.7%. The incidence density for the Duhamel procedure was 35.1 SBOs per 1000 patient-months of follow-up. Of the two obstructed patients, one (50.0%) had an anastomotic leak followed by an episode of generalized peritonitis. All of these patients were younger than 15 months of age.

Statistical Analysis of Kaplan-Meier Incidence Curves

When the Kaplan-Meier incidence curves for SBO following each of the nine abdominal procedures were compared, a generalized Breslow-Cox p value < 0.00005 revealed a definite, statistical difference.

When the incidence curves were compared between appendectomy, splenectomy and cholecystectomy procedures (Figure II), there was a Breslow-Cox p value < 0.0134, indicating a statistically significant difference in the rate of small bowel obstruction for these three procedures. When only the appendectomy and cholecystectomy curves were compared, there was a Breslow-Cox p value < 0.0277, indicating again a statistically significant difference in the rate of small bowel obstruction. There was also a statistically significant difference between the splenectomy and cholecystectomy obstruction curves, with a Breslow-Cox p value < 0.0018.

When comparing the obstruction incidence curves of colostomy and TAH procedures (Figure III), both of which included many cancer patients in the cohort, there was a Breslow-Cox p value < 0.0662, a nearly statistical difference.

There was a Breslow-Cox p value < 0.1599 when the incidence curves of TAH and vaginal hysterectomy were compared, suggesting a trend towards significance.

Descriptive Analysis

Demographics

Of the 58 patients returning with small bowel obstruction, 21 (36.2%) were male and 37 (63.8%) were female. Table IV shows the sex distribution relative to the cancer status of each patient. There were 15 (46.9%) males and 17 (53.1%) females without cancer as compared to 6 (23.1%) males and 20 (76.9%) females with cancer. The chi-square p value (p = 0.061) demonstrated a nearly statistically significant difference between the gender distributions for those with and without cancer.

The average age for the group of patients returning with small bowel obstruction was 54.3 years. However, when the patients presenting with small bowel obstruction were separated into those with and without cancer, the average age was 62.8 years and 47.3 years, respectively. These two age distributions were statistically significant, with a Cochran's method p value < 0.005. The age distributions for patients with and without cancer are depicted graphically in Figures IV and V.

Surgical Histories

Table Va depicts the total number of abdominal procedures performed on obstructed patients, both with and without cancer, prior to the indexing abdominal operation which identified patients as members of the cohort. For patients without cancer, 17 (53.1%) had no previous abdominal surgery, whereas 13 (40.6%) had one previous abdominal surgery and two (6.3%) had two previous abdominal surgeries. For patients with cancer, 13 (50.0%) had no previous abdominal surgery and 13 (50.0%) had only one previous abdominal surgery. Statistically, there were no significant differences between these numbers.

Table Vb outlines the total number of subsequent abdominal procedures performed on cancer patients and cancer-free patients since entering the cohort (excluding the indexing procedure). Among the obstructed cancer patients, six (23.1%) underwent subsequent abdominal surgery following their index procedure for additional resection of cancer; whereas among the obstructed cancer-free patients, only two (6.3%) required subsequent abdominal procedures. This difference was statistically significant, with a p value = 0.026 by the Fisher's exact test. Of the six obstructed cancer patients, four (66.7%) had exploratory laparotomy and debulking of tumor, one (16.7%) had colectomy, and one (16.7%) had total gastrectomy. Among the two obstructed cancer-free patients, both (100.0%) had exploratory laparotomy.

The average total number of hours of surgery, including index procedure, for all obstructed patients since entering the cohort was 3.0 hours. However, when the patients

were separated into those with and without cancer (Table VI), the average total hours of surgery since entering the cohort was 3.5 hours and 2.6 hours, respectively. With the p value < 0.0005 by Cochran's method, there was a significant difference in the average total number of hours of surgery received.

Treatment of SBO: Modality and Duration

The various modes of treatment received by patients with early SBO and delayed SBO are outlined in Table VII. Long tube therapy was successful for 43.1% of the patients with delayed SBO and 42.9% of the patients with early SBO.

Table VIII shows the average duration of hospitalization for patients with and without cancer who presented with delayed SBO. There were no significant differences between cancer patients and cancer-free patients with regard to the average length of hospitalization when they each received the same type of treatment for obstruction. There was, however, a statistically significant difference in duration of hospitalization between the different types of treatment undertaken. Although the average length of stay for immediate surgical treatment and the average length of stay for surgery after failed long tube therapy were not significantly different from each other, each differed from the average length of stay for those patients who received successful long tube therapy alone (p value < 0.005).

Cancer Histology

There were 26 patients with a history of cancer who presented with small bowel obstruction secondary to cancer. This represented 44.8% of all patients presenting with small bowel obstruction from the postoperative cohort. Thirteen (50.0%) of these cancer patients had a primary gynecological carcinoma, of which eight (30.8%) were ovarian primaries and five (19.2%) were uterine primaries. Colon carcinoma accounted for 10 (38.5%) of the cancer patients who presented with small bowel obstruction. Two (7.7%) of the cancer patients with SBO had gastric cancer. Lymphoma caused one (3.8%) of the patients with cancer to return with small bowel obstruction (Table IX).

Early versus Delayed SBO and Most Recent Abdominal Procedure

Table X records the type of small bowel obstruction for patients with and without cancer. Of those patients without cancer, 25 (78.1%) of the patients had delayed small bowel obstruction and seven (21.9%) had early small bowel obstruction. Of those patients with cancer, all 26 (100.0%) of the patients had delayed small bowel obstruction and none (0.0%) had early small bowel obstruction. There were no significant differences between these figures.

Of those patients who had early small bowel obstruction, three (42.9%) had a preceeding colectomy; three (42.9%) had a preceeding exploratory laparotomy; and one (14.3%) had a preceeding total abdominal hysterectomy (Table XI).

Table XII shows the most recent abdominal procedure performed on patients both with and without cancer who presented with delayed small bowel obstruction. For patients without cancer, five (20.0%) had colon surgery; four (16.0%) had total abdominal hysterectomy; three (12.0%) had cholecystectomy; two (8.0%) had exploratory laparotomy; two (8.0%) had appendectomy; two (8.0%) had splenectomy; and one (4.0%) had gastrectomy. For patients with cancer, nine (34.6%) had colon surgery; seven (26.9%) had total abdominal hysterectomy; four (15.4%) had exploratory laparotomy; and two (7.7%) had gastrectomy. Statistically, there were no differences between these two groups.

Mortality

There were no in-hospital deaths among the patients presenting with small bowel obstruction in this study; thus a mortality rate of 0.0%. However, six (10.3%) of the patients with SBO were discharged to Hospice in terminal condition. All six patients with terminal obstruction originally presented with delayed small bowel obstruction and had a history of cancer. These six patients constituted 23.1% of all patients with cancer in this study. Four (66.7%) of the patients discharged to Hospice had ovarian cancer; one (16.7%) had uterine cancer; and one (16.7%) had colon cancer.

History of Abdominal Radiation Therapy

Among the cancer patients returning with small bowel obstruction, ten (38.5%) had some form of radiation therapy directed towards the abdomen prior to the first small bowel obstruction.

Multiple Obstructions

Of all patients returning with small bowel obstruction from the postoperative cohort, 13 (22.4%) developed multiple obstructions over time. Of these patients who developed multiple obstructions, ten (76.9%) had a history of cancer, of which five (38.5%) had an additional history significant for radiation therapy. The remaining three (23.1%) patients who presented multiple times with SBO each had total abdominal hysterectomies with no history of cancer.

DISCUSSION

This study represents the first time that Kaplan-Meier product-limit analysis has been applied to the study of postoperative small bowel obstruction. By retrospectively defining a postoperative surgical cohort and following the group forward in time, observing for small bowel obstruction, life table analysis generated incidence curves for postoperative SBO following selected abdominal procedures. These Kaplan-Meier product-limit incidence curves take into account the relative duration of follow-up for each cohort patient. Figure I depicts these incidence curves for those patients in the cohort who did not suffer an obstructing event. From these data, incidence densities were calculated which allowed valid comparisons of obstruction rates between the various surgical procedures. The novelty of this study rests in the methodology: This approach examined an old issue and revealed new information. Previous studies had been mainly descriptive in nature by only characterizing the obstructed group and failing to look at the entire population at risk. Furthermore, those previous studies which quoted incidence rates, when examined closely for statistical soundness, failed to be consistent in statistical approach.

Strengths of the Kaplan-Meier Methodology

The strength of the Kaplan-Meier product-limit method is demonstrated by analyzing the data obtained in the present study using the techniques of previous studies.

For example, there were 179 appendectomies performed in fiscal year 1986 at Yale-New Haven Hospital of which 41 patients returned for follow-up and three developed SBO over the ensuing six years (Table III). Using *heterodemic* techniques, this means that for appendectomy, there were 3 SBOs per 230,000 population in the New Haven region over six years, or 0.00022% of population per year. This is obviously a meaningless figure

because not every person in the denominator is at-risk for post-appendectomy SBO nor is there any accounting for loss to follow-up. A slightly more refined statistic, although still quite *heterodemic*, is an incidence of 3 SBOs per 179 appendectomies performed, or 1.7%. Although this figure attempts to account for only those patients at risk for post-appendectomy SBO, it is still of little value because it assumes that all 179 appendectomy patients are still alive and would return exclusively to Yale-New Haven Hospital for treatment of obstruction. This is obviously an invalid assumption. A crude estimate of the incidence of SBO after appendectomy, which attempts to take follow-up into account, is an incidence of 3 SBOs per 41 observed patients over six years, or 7.3%. This value actually represents the percentage of patients receiving follow-up who become obstructed; however, it is neither a true rate, nor does it account for varying duration of follow-up. Using Kaplan-Meier product-limit analysis, the incidence of obstruction, adjusted for duration of follow-up after appendectomy, is 10.7% during 5.3 years of follow-up. This accounts for the varying duration of follow-up in the cohort.

Thus these different statistical methods all produce "incidence rates" for postoperative obstruction. It is only the Kaplan-Meier method, however, which accounts for loss to follow-up and duration of follow-up in the at-risk population.

Rates of Obstruction Vary with Abdominal Procedure

Various abdominal procedures resulted in statistically different rates of small bowel obstruction over time. Although this was suspected in earlier studies, only through cohort data analysis could this be statistically defined. It must be noted, however, that three procedures examined in the present study (Duhamel, APR, and gastroenterostomy) had fewer than ten patients in each cohort. The importance of this fact is discussed in depth later.

Colostomy

Colostomy had an obstruction rate of 30.8% during 69 months of follow-up and an incidence density of 8.3 SBOs per 1000 patient-months of follow-up. This means that 30.8% of the patients who underwent colostomy were obstructed by 69 months of follow-up.

Of those patients who presented with SBO after colostomy, 71.4% had the indexing abdominal procedure for cancer. This implies that it was the cancer (*i.e.* - the indication for the procedure), rather than the operative procedure itself, which caused patients to return with obstruction. However, to properly resolve this issue, future studies need to divide the entire cohort, not just those presenting with obstruction, into two additional cohorts: those who undergo colostomy for cancer and those who undergo colostomy for other reasons (*i.e.* - inflammatory bowel disease). Then, using follow-up data for these two sub-cohorts, Kaplan-Meier product-limit analysis could be applied to determine the incidence of obstruction for those undergoing colostomy both with and without cancer.

TAH / APR / Splenectomy

Total abdominal hysterectomy (TAH), abdominoperineal resection (APR) and splenectomy were the next most obstruction-prone surgeries, with incidence rates of 18.2% during 70 months of follow-up, 14.3% during 53 months of follow-up, and 11.2% during 65 months of follow-up, respectively. Incidence densities were 4.1, 4.0 and 4.1 SBOs per 1000 patient-months of follow-up, respectively.

These results are intriguing because whereas APR is always associated with cancer and TAH may or may not be associated with cancer, splenectomy is usually associated with a cancer-free state. This implies that the high incidence of obstruction associated with splenectomy is due to some inherent adhesion formation associated with this particular type of surgery. For example, when the spleen is dissected off of the diaphragm, a raw surface is left where blood may tend to pool. This may predispose patients to adhesion formation. Moreover, the situation in which splenectomy is indicated (*i.e.* - trauma) may predispose

patients to adhesion formation, perhaps because the bowel is not prepped or a ruptured viscus may be concomitantly present. Although there are certain cases where splenectomy may be indicated for staging of cancer (*e.g.* - Hodgkins Disease), no such staging procedures were included in the observed, postoperative cohort. The incidence curves for obstruction following splenectomy (Figures I and II) also demonstrate a statistically significant front-loaded risk, in other words, obstruction in this cohort tended to manifest very early in comparison to other procedures.

In the present study, cohort patients who underwent TAH included patients both with and without a history of gynecological cancer. In fact, 57.1% of the patients who presented with obstruction from the TAH cohort also had a history of cancer. Thus the calculated incidence of obstruction following TAH may be somewhat inflated because the cohort included both cancer and cancer-free patients. Future studies should separate the entire TAH cohort, not just those presenting with obstruction, into those who underwent TAH for cancer and those who underwent TAH for other reasons (*e.g.* - fibroids, endometriosis). In this manner, a Kaplan-Meier product-limit incidence would be derived for these two distinct groups.

As far as APR is concerned, 14.3% of the patients developed SBO after 53 months of follow-up. Obstructions in this group of patients were secondary to recurrent cancer; not a surprising fact given the indications for APR. This calculated incidence figure is close to the incidence quoted by Sannella of 10.8%, although he does not describe his methodology or duration of follow-up.[42]

This raises an interesting issue, for APR, which includes colostomy, in fact has a lower rate of obstruction than isolated colostomy (14.3% during 53 months versus 30.8% during 69 months). With respect to obstruction secondary to recurrent cancer, this may be due to better curative resection with APR. Of course, to properly resolve this issue, future studies must subdivide the colostomy cohort into those with and without cancer as discussed

above. Another reason for this finding may be sample size bias, for the APR cohort had only nine pateints.

The incidence densities for TAH, APR and splenectomy were nearly equal. This implies that although the rates of obstruction were different, given the size of each cohort and the total amount of follow-up time, the overall density of events was similar. This is explained by the front-loaded risk of obstruction associated with splenectomy (n=20) as compared to the more static risk associated with TAH (n=121): Although the rates were different, over time, the densities were similar.

Appendectomy

Many previous studies[28,30,32,38,39] list appendectomy as a significant cause of small bowel obstruction in the postoperative patient. Unfortunately, these studies lack a cohort and incorrectly base their assumptions solely on returning patients with small bowel obstruction rather than looking at all patients at risk. Since appendectomy is a common procedure, studies which look only at returning patients with obstruction, and not entire at-risk populations, will assume the incidence of obstruction following appendectomy is much higher than it truly is, because the appendectomy patients are disproportionately represented due to the prevalence of the procedure. The present study demonstrated an incidence of obstruction after appendectomy of 10.7% after 64 months of follow-up and an incidence density of 2.2 SBOs per 1000 patient-months of follow-up.

Although the incidence of obstruction following appendectomy was not significantly different from that of splenectomy (10.7% over 5.3 years versus 11.2% over 5.4 years), the incidence density was lower (2.2 versus 4.1 SBOs per 1000 patient-months of follow-up). This reflects the large numbers of patients with greater duration of follow-up who underwent appendectomy compared to splenectomy. Thus previous studies cite appendectomy as a significant cause of SBO only because it is a common procedure which accordingly results in more obstructed patients, but actually its incidence of obstruction is similar to that of splenectomy.

Another issue raised by this study is that 66.7% of the patients with small bowel obstruction who originally underwent appendectomy had a perforated appendix at the time of initial procedure. This implies that the contaminated surgery associated with a perforated abdominal viscus may in fact cause greater adhesion formation and a higher rate of obstruction. However, to accurately explore this question, future studies must separate out the entire appendectomy cohort, not just those presenting with obstruction, into those with clean and those with contaminated surgery. Kaplan-Meier analysis would then allow comparison of the obstruction incidence of these two sub-cohorts.

Cholecystectomy

Cholecystectomy had a low obstruction incidence of 6.4% during 67 months of follow-up with an incidence density of 0.7 SBOs per 1000 patient-months of follow-up. This obstruction rate is significantly lower than that of colostomy, TAH, appendectomy or splenectomy. Thus of all the common abdominal surgery performed, cholecystectomy was the least obstruction-prone procedure in the abdomen. Additionally, the calculated incidence density reflects the relative dearth of obstruction given the large at-risk population which received follow-up. This is an intriguing finding, because anatomically, the field of dissection required to reach the gallbladder and its fossa presumably involves less direct manipulation of bowel. It therefore implies that there is an irreducible minimum rate of small bowel obstruction, secondary to adhesion formation, for just entering the abdomen.

Gastroenterostomy

The cohort which underwent gastroenterostomy had an incidence of obstruction equal to 0.0% during 11 months of follow-up and an incidence density of 0 SBOs per 1000 patient-months of follow-up. This cohort, however, was not very large nor was it observed for a long time. Although this calculated incidence of obstruction is in fact accurate for those patients who underwent gastroenterostomy at Yale-New Haven Hospital in fiscal year 1986, given the small sample size and potential for sample size bias, whether or not this incidence is applicable to the general gastroenterostomy population is questionable. To

produce statistically significant results, future studies should observe more of these patients for a greater duration of time.

Vaginal Hysterectomy

The vaginal hysterectomy cohort had an incidence of obstruction equal to 0.0% during 70 months of follow-up and an incidence density of 0 SBOs per 1000 patient-months of follow-up. Previous studies have shown hemorrhage, vaginal cuff cellulitis, uterovaginal fistula, vesicovaginal fistula and enterovaginal fistula to be recognized complications of vaginal hysterectomy; however, no studies have examined the postoperative incidence of SBO.[1,20] This begs the question of whether or not vaginal hysterectomy in fact produces fewer obstructing adhesions than total abdominal hysterectomy. Statistical comparison of the incidence of postoperative SBO for these two hysterectomy procedures produced a p value = 0.1599, suggesting a trend, but not proving that there is in fact a difference between obstruction rates. This is because the number of patients receiving follow-up after vaginal hysterectomy was too few: whereas 14 of 121 patients became obstructed following TAH, 0 of 15 patients became obstructed following vaginal hysterectomy. To fully answer this question, future studies must observe a larger cohort of women who undergo vaginal hysterectomy. Additionally, a more powerful statistic would result by separating out those women who underwent TAH and were cancer-free, and comparing their rate of obstruction to those women who underwent vaginal hysterectomy and were also cancer-free.

Duhamel Procedure

The present study demonstrated that the Duhamel pull-through procedure for Hirschsprung's disease in children had the highest rate of subsequent obstruction. The incidence rate of small bowel obstruction was 66.7% during 36 months of follow-up with an incidence density of 35.1 SBOs per 1000 patient-months of follow-up. This incidence density was high, implying that these obstructing events occurred during a relatively short amount of follow-up time.

Of interest is the particularly high obstruction rate obtained in the present study. One reason may be the small size of the cohort which underwent the Duhamel procedure. Unpublished data from the Section of Pediatric Surgery at Yale-New Haven Hospital revealed three obstructions from 44 Duhamel procedures performed over the past 16 years.[43] Unfortunately, these data do not include duration of follow-up for each patient and, therefore, a true incidence rate cannot be calculated without further review. This does demonstrate, however, that the observed cohort in the present study happened to contain most of the children who were re-admitted to Yale-New Haven Hospital with subsequent small bowel obstruction following Duhamel procedure. Therefore, given the small cohort size in the present study, there may be sample size bias. Hence the calculated incidence figure, although accurate for all patients who underwent Duhamel procedure at Yale-New Haven Hospital in fiscal year 1986, may not be applicable to the general population who underwent this procedure. To appropriately address this issue, future studies should include a greater number of observed patients in this cohort.

SanFilippo reported that 14.3% of the patients in his study who underwent the Duhamel procedure and were then followed-up in clinic, returned with postoperative small bowel obstruction secondary to adhesions.[41] However, SanFilippo did not account for the duration of follow-up: thus this number does not represent an actual incidence rate over time, but rather a proportion of patients receiving follow-up who then developed obstruction. Nevertheless, it does demonstrate that obstruction is in fact a significant risk with this procedure. Perhaps this is because the Duhamel procedure consists of two separate abdominal operations, each with it's own risk for adhesion formation, or perhaps the remaining aganglionic intestine behaves differently with regard to adhesion formation.

In the present study, one of the two obstructed patients who underwent Duhamel procedure had an anastomotic leak. This implies that postoperative contamination of the peritoneal cavity predisposes patients to adhesion formation and subsequent obstruction. To properly answer this question, however, future studies should separate out the entire

Duhamel procedure cohort, not just those presenting with obstruction, into those patients with and without postoperative anastomotic leak. Kaplan-Meier product-limit analysis would then demonstrate whether or not a difference existed in subsequent rates of SBO between these two groups.

Potential Shortcomings of the Kaplan-Meier Methodology

Surgeons may be initially surprised at the incidence figures for small bowel obstruction following the various abdominal procedures as tabulated in the present study. However, to arrive at an accurate incidence figure, rigorous calculations must be respected, for rates derived from personal experience without regard to chart review and follow-up are subject to recall bias.

The calculated incidences of obstruction following either the Duhamel procedure, APR or gastroenterostomy, although accurate for cohort patients at Yale-New Haven Hospital in fiscal year 1986, may not be representative of the general population. This is because these cohorts had fewer than ten patients each. Although the Kaplan-Meier product-limit analysis is accurate for such small samples, the number of patients studied may not be large enough to guarantee an unbiased sample which is representative of the general population undergoing these procedures. Future studies should increase the observed cohort sizes.

On the other hand, the calculated incidences of SBO for patients following either colostomy, TAH, appendectomy or cholecystectomy were based on significantly larger cohorts, eliminating any potential for sample size bias (greater than 30 patients each). The cohorts which underwent vaginal hysterectomy and splenectomy both had fewer patients, 15 and 20 respectively, but nevertheless each had enough patients to create an unbiased group. Therefore these incidence rates, although they may appear greater than expected to surgeons, are in fact statistically sound.

The incidence values of obstruction following colostomy and TAH are high because cancer patients were not separated out from these cohorts prior to Kaplan-Meier analysis. Therefore, these rates reflect both mechanical and cancerous obstruction in the cohort. To resolve this issue, all cohort patients (not just those presenting with obstruction) need to be individually examined for a history of cancer: this is beyond the scope of the study.

One assumption used in calculating the Kaplan-Meier product-limit, as outlined in the Materials and Methods section, was that those patients who were subsequently re-admitted to Yale-New Haven Hospital were in fact dedicated users of the hospital, until they went elsewhere and were lost to follow-up. In other words, follow-up data were based on most recent hospital admission data and discharge diagnoses. This is a valid assumption, because those postoperative cohort patients who returned to Yale-New Haven Hospital demonstrated a preference for this hospital. Additionally, Yale-New Haven Hospital is not solely a tertiary care center based on regional referrals, but rather one of only two local hospitals. Potential for bias in work-up, diagnosis and therapy was eliminated by excluding all cohort patients who were diagnosed with SBO at any other hospital or were transferred to Yale-New Haven Hospital.

It is possible that a few patients may have undergone their indexing primary procedure at Yale-New Haven Hospital, had an obstructing event treated at an outside hospital, and then returned to Yale-New Haven Hospital for treatment of another ailment. This subgroup of cohort patients would not have been tabulated in the obstructed group, but would have been counted as receiving follow-up which was free of obstruction. Despite eventual follow-up at Yale-New Haven Hospital, there would be no way to know of their prior obstruction.

Some might argue that basing Kaplan-Meier product-limit analysis on follow-up data obtained from hospital re-admissions skews the analysis towards a sicker cohort of patients. However, simple, mechanical small bowel obstruction is an independent event which occurs only as a result of adhesion formation and subsequent band contraction.

Thus other medical problems requiring hospital admission (*e.g.* - seizures, asthma, stroke, renal failure) should not select out a biased population with regard to the incidence of simple, mechanical SBO. This is an important assumption, for if the calculated incidence rates of postoperative obstruction are to be applied to the general, at-risk population, all patients lost to follow-up must possess a similar underlying incidence of SBO to the population which received follow-up. Nevertheless, to improve the statistical strength of this assumption, future studies should incorporate direct follow-up of all patients (*i.e.* - letters and phone calls to contact patients in the cohort) for the calculation of Kaplan-Meier incidence rates. If, on the other hand, the population lost to follow-up was indeed healthier and experienced a lower rate of simple, mechanical SBO than the population which received follow-up, then the calculated incidence rates of SBO in the present study represent maximum values.

This study only examined nine operative procedures using the Kaplan-Meier product-limit method (appendectomy, colostomy, TAH, vaginal hysterectomy, cholecystectomy, splenectomy, APR, Duhamel procedure and gastroenterostomy). Although this represents many of the procedures which obstructed patients had most recently undergone, future studies should examine Kaplan-Meier product-limit incidence rates for other procedures, such as exploratory laparotomy, colectomy, abdominal aortic aneurysm repair and urological procedures.

Many of the patients in the present study had quite complex surgical histories, with a record of either abdominal surgery before entering the cohort, abdominal surgery since entering the cohort, or both. Previous studies of small bowel obstruction failed to even address this observation.[4,6,13,14,22,25,27,37,39] In the present study, the most recent abdominal procedure was used to calculate the Kaplan-Meier product-limit incidence. Ideally, future studies should look at postoperative patients with previously pristine surgical abdomens and tabulate incidence rates of SBO. These results should be compared to those obtained in this study, in order to assess any difference in the rate of obstruction

between first-time and multiple-time operated abdomens. Furthermore, multivariate analysis might be helpful in analyzing any additional risk for obstruction in patients who underwent multiple abdominal procedures.

This study relied on ICD-9 codes for computer searches of the data base. These codes were used to both (1) flag patients who received an indexing procedure into the cohort and (2) scan for cohort patients who were re-admitted to the hospital. The ICD-9 codes for admitting diagnoses of all patients at Yale-New Haven Hospital are entered into the data base by personnel in the Quality Assurance Department based on the Patient Summary Sheet filled out by attending physicians for each patient upon discharge. Additionally, ICD-9 codes for all operative procedures are entered into the data base by personnel in the Quality Assurance Department from daily operative records. It is therefore unlikely that the ICD-9 codes are subject to any significant type of bias, given the method in which these codes are entered into the data base.

The incidence rate of small bowel obstruction over time following any one of nine abdominal procedures was calculated in this study. Thus, for example, this study now permits surgeons to inform their patients that the risk over 64 months for obstruction after appendectomy is 10.7% (*i.e.* - 10.7 patients out of 100 who received follow-up for 5.3 years after undergoing appendectomy developed obstruction at some point in time). However, data beyond this time period does not exist. Although the incidence of obstruction appears to be a front-loaded risk (Figure I), with most obstructing events occuring earlier, rather than later, the fact that the incidence curves plateau between 40 and 55 months does not mean that obstructions will no longer occur beyond that point in time. Incidence rates cannot be extrapolated beyond the duration of follow-up because the rate of obstruction may not be constant over time. To supply obstruction data beyond the follow-up time, future studies must again look at this cohort after additional follow-up time has elapsed.

Descriptive Analysis of Obstructed Patients

Early Small Bowel Obstruction

Several previous studies have addressed the percentage of small bowel obstructions which occur within 30 days of surgery. Some authors quote ranges as wide as 10% - 50% for early small bowel obstruction,[50] whereas others support narrower ranges from 5% - 29%.[18] Laws calculated that 22.3% of the postoperative obstructions in his study were of the early type.[25] In the present study, 12.1% of the obstructions were classified as early, adding more evidence that the lower range of these previous estimates is more accurate. Of additional interest is that in this study, none of the early small bowel obstructions was associated with cancer recurrence. Quan had similar findings in his study.[36]

Carcinoma and Mortality

Table XIII illustrates the percent of small bowel obstructions secondary to carcinoma in several major studies, including this one. What becomes evident is not only the varying percentage of patients who present with obstruction secondary to cancer, but the universally high mortality rate among these obstructed cancer patients. Another interesting fact is that although our study contains the greatest percentage of patients obstructed secondary to cancer, none died in the hospital. This is because six of the cancer patients (23.1%) were discharged in terminal condition and allowed to die at Hospice. In an era of cost containment and death with dignity, this is an important issue which deserves further review.

Overall mortality rates from previous studies among all patients presenting with small bowel obstruction during the past century are listed in Table XIV. A sharp decrease in mortality may be noted during the late 1930s and early 1940s. This is not due to the introduction of antibiotics, but rather the introduction of the long intestinal tube as treatment for obstruction. Furthermore, with better understanding of fluid balance and the use of intravenous hydration, the mortality rates decreased even further.[14] The fact that this study

had a mortality rate of zero is significant, for it demonstrates that although small bowel obstruction is still associated with morbidity, it may be no longer necessarily associated with hospital mortality.

Obstructed Cancer Patients v. Obstructed Cancer-free Patients

Differences between the postoperative, obstructed, cancer population and the postoperative, obstructed cancer-free population emerge from this study. There is nearly a statistically significant difference (p value = 0.061) in the sex distributions between those patients with and without cancer (Table IV). This is due to the high number of gynecological patients with cancer who presented with obstruction after their indexing surgery.

Similarly, there is a statistically significant difference in the average age between those obstructed patients with and without cancer (62.8 years and 47.3 years, respectively, p value < 0.005). This is because the underlying population of cancer patients is, in fact, older.

The average, obstructed, cancer patient received significantly more hours of surgery since entering the cohort than the average, obstructed, cancer-free patient (3.5 hours and 2.6 hours, respectively, p value < 0.0005, Table VI). Furthermore, although these obstructed cancer patients did not have a past surgical history significantly different from the obstructed cancer-free patients prior to entering the cohort (Table Va), the obstructed cancer patients in fact had a significantly greater number of subsequent abdominal procedures performed once they entered the cohort (Table Vb, p value = 0.026). The most likely explanation is that despite similar past surgical histories, once diagnosed with cancer, these cohort patients required both more hours of surgery for exterpative procedures and a greater number of procedures overall for recurrence.

Data from this study illustrate that there are no statistical differences in the duration of hospitalization for the treatment of SBO between obstructed cancer patients and obstructed cancer-free patients (Table VIII). This implies that these two obstructed patient groups -

those with and without cancer - are treated no differently by surgeons in regard to duration of hospitalization. Not surprisingly, the data did show that those patients who received successful tube therapy had a statistically shorter hospital stay than all other forms of therapy. On the other hand, there was no statistical difference in duration of hospital stay between those patients who underwent immediate surgery and those who underwent surgery after failed intestinal tube therapy. These data are important as issues of cost containment are raised by hospital administrators.

Among the cancer patients presenting with small bowel obstruction from the postoperative cohort, 38.5% received prior radiation therapy to the abdomen. Contributing to this high percentage may be the fact that many of the cancer patients at Yale-New Haven Hospital received this type of treatment. Exposure to abdominal radiation is widely considered to increase the rate of obstruction.[3,15,50] Although Helmkamp had a similar result of 47.8%,[21] future studies should assess the amount of radiation therapy received by all cohort patients in order to perform Kaplan-Meier product-limit analysis. Then statistically accurate incidence rates of postoperative small bowel obstruction with and without prior abdominal radiation therapy could be calculated. Nevertheless, these results imply that abdominal radiation therapy is a significant risk factor for subsequent small bowel obstruction.

Of the obstructed cancer patients, 13 (50.0%) had a gynecological cancer, ten (38.5%) had colon cancer, two (7.7%) had gastric cancer and one (3.8%) had lymphoma (Table IX). These results suggest that both gynecological cancer - especially ovarian and uterine carcinomas - as well as colon cancer may produce significant obstruction despite previous surgical management. However, to find out a statistically significant incidence rate of obstruction for these cancers, future studies must define and follow-up a cohort of patients with various types of cancer, who are at risk for obstruction, and apply Kaplan-Meier product-limit analysis.

One potential source of bias is the method in which cohort patients with cancer, who returned obstructed, were classified as having an obstruction secondary to cancer rather than adhesions. As outlined in the Materials and Methods section, cohort patients with a history of cancer and who returned to Yale-New Haven Hospital obstructed, were considered to have an obstruction secondary to adhesions only if there was either (1) no evidence of recurrence at surgery to relieve the obstruction or (2) the obstruction resolved in fewer than five days and there was no evidence of cancer recurrence in the medical records. These are rigid parameters. Therefore, some cancer patients who had obstruction secondary to adhesions, may in fact, had their obstruction incorrectly labeled as secondary to cancer. Although methodologically sound, this might inflate the number of obstructed patients reported as having obstruction secondary to carcinoma. This might contribute to the high obstruction rate secondary to carcinoma, found in the present study, as compared to previous studies (Table XIII).

Treatment of Patients with Small Bowel Obstruction

Table XV compares the treatment of postoperative patients presenting with both early and delayed small bowel obstruction in previous studies as well as in this study. All of these studies had a similar percentage of success with intestinal intubation in the treatment of SBO: From 37.5% - 40.4% for cancer-free, delayed SBOs to 42.3% - 73.2% for all-comers with early SBOs. This implies that there is a certain, constant percentage of small bowel obstructions which are treatable with intestinal tube therapy. Thus it appears reasonable that if there are no signs of intra-abdominal catastrophe, postoperative patients with small bowel obstruction deserve a trial of hydration and intestinal tube therapy. This is indeed standard practice. Surgical intervention is indicated only if there are signs of intestinal strangulation or failure to revert obstruction with intubation.

Role of Perforated Viscus in Subsequent Small Bowel Obstruction

Perforation of an abdominal viscus appears to increase the risk for subsequent SBO. This is presumably mediated by an increase in adhesion formation within a contaminated

peritoneal cavity.[3] Two of three obstructed patients who had undergone appendectomy had perforated appendix preoperatively, one of three obstructed patients who had undergone cholecystectomy had perforated gallbladder preoperatively, and one of two obstructed patients who had undergone Duhamel procedure developed anastomotic leak postoperatively. Of course true obstruction rates following peritoneal contamination cannot be calculated from these figures, nevertheless, these numbers suggest an increased risk for subsequent SBO exists. To settle this issue, future studies should perform Kaplan-Meier product-limit analysis on patients with and without gross peritoneal contamination and compare the resulting incidence rates of obstruction. Additionally, Kaplan-Meier product-limit analysis should be used to examine whether or not incidental enterotomies increase the postoperative incidence of small bowel obstruction.

Multiple Obstructions

Of the patients returning with small bowel obstruction, 22.4% subsequently developed multiple obstructions. Furthermore, 76.9% of these patients with multiple obstructions had a history of cancer, with 38.5% of these patients having been exposed to prior radiation therapy. The remaining 23.1% of the patients with multiple obstructions, although cancer-free, all had total abdominal hysterectomies.

This is an intriguing finding which should be examined in greater depth. Primarily, it suggests that cancer is a significant risk factor for multiple events. Additionally, radiation therapy appears to be linked with multiple obstructions; although on the other hand, it may simply reflect a tendency to use radiation therapy among these cancer patients. To address these issues in a proper statistical fashion, a cohort of patients with specific types of cancer should be defined and observed over time for radiation therapy and obstruction. Kaplan-Meier product-limit analysis could then be applied to calculate incidence rates.

For cancer-free patients, either TAH is an operative procedure inherently associated with multiple obstructions or there may be some intrinsic difference between patients who experience multiple obstructions and those who do not. Future studies undertaking

multivariate logistic analysis of the cohort could elucidate relative risk factors associated with multiple obstructions.

Most Recent Abdominal Procedure Performed

Tables XVI and XVII compare the most recent abdominal procedure performed in patients presenting with either early or delayed small bowel obstruction in studies from the past 40 years. Colon and gynecological surgeries head each list as being the most recent procedure performed on patients presenting with small bowel obstruction. However, these percentages represent only proportions of the most recent operative procedure performed on patients who subsequently developed obstruction. For example, although McEntee found that 25% of the patients in his study who presented with small bowel obstruction had previous appendectomies, this figure does not relate at all to the incidence of obstruction following appendectomy. These types of statistics fail to account for the entire at-risk population. As discussed above, the only method to produce a statistically accurate incidence rate is a cohort study that assesses all patients at risk, not just those who present after an event.

Conclusions

This study demonstrated the power of Kaplan-Meier product-limit analysis as applied to small bowel obstruction in postoperative patients. Through cohort analysis of all patients at risk for SBO after selected abdominal procedures, incidence rates and incidence densities of small bowel obstruction were obtained. No other study has evaluated postoperative obstruction using this statistical methodology.

In the present study, the Duhamel procedure was associated with the greatest incidence of subsequent SBOs, 66.7% during 3.0 years of follow-up (n=3). Colostomy had the next highest incidence of obstruction, 30.8% during 5.8 years of follow-up (n=34); total abdominal hysterectomy with 18.2% during 5.8 years (n=121); abdominoperineal resection

with 14.3% during 4.4 years (n=9); splenectomy with 11.2% during 5.4 years (n=20); appendectomy with 10.7% during 5.3 years (n=41); and cholecystectomy with 6.4% during 5.6 years (n=141). Both gastroenterostomy (n=8) and vaginal hysterectomy (n=15) were not associated with any obstructions in this study.

It must be noted, however, that the incidence rates obtained for Duhamel procedure, APR and gastroenterostomy are not necessarily applicable to the general population given the small sample sizes.

This study also produced data which showed differences between obstructed cancer patients and obstructed, cancer-free patients. These differences included average age as well as average total hours of surgery and number of subsequent operative procedures since entering the cohort. Differences in gender were nearly statistically significant. There were in fact no differences between these two groups with regard to past surgical histories or duration of hospitalization for similar treatment of SBO. For both groups, duration of hospitalization was significantly shorter with successful intestinal intubation as treatment for SBO. Additionally, there were no in-hospital deaths among either of these two groups, although nearly one quarter of the obstructed cancer patients were discharged to Hospice in terminal condition.

As laparoscopic surgical techniques improve, questions will arise as to the long term sequelae - including the potential for postoperative adhesion formation. This study represents the only statistically thorough review of obstruction secondary to adhesion formation for open abdominal procedures - including cholecystectomy and appendectomy. Therefore this review may serve as a comparison for future studies of laparoscopic adhesion formation and obstruction.

The present study also has significant legal applications. For the first time, statistically accurate incidence values over time for postoperative obstruction are reported for nine abdominal procedures, of which six are quite commonly performed. It must be stressed that the data cannot be accurately extrapolated beyond the recorded follow-up time.

However, the reported incidence figures represent expected complications of abdominal surgery secondary to adhesion formation.

Future applications of this methodology could answer the many issues raised concerning postoperative bowel obstruction. Furthermore, this methodology could be applied to a vast range of general surgical problems not yet addressed, including obstructions secondary to wound contamination and inflammatory bowel disease.

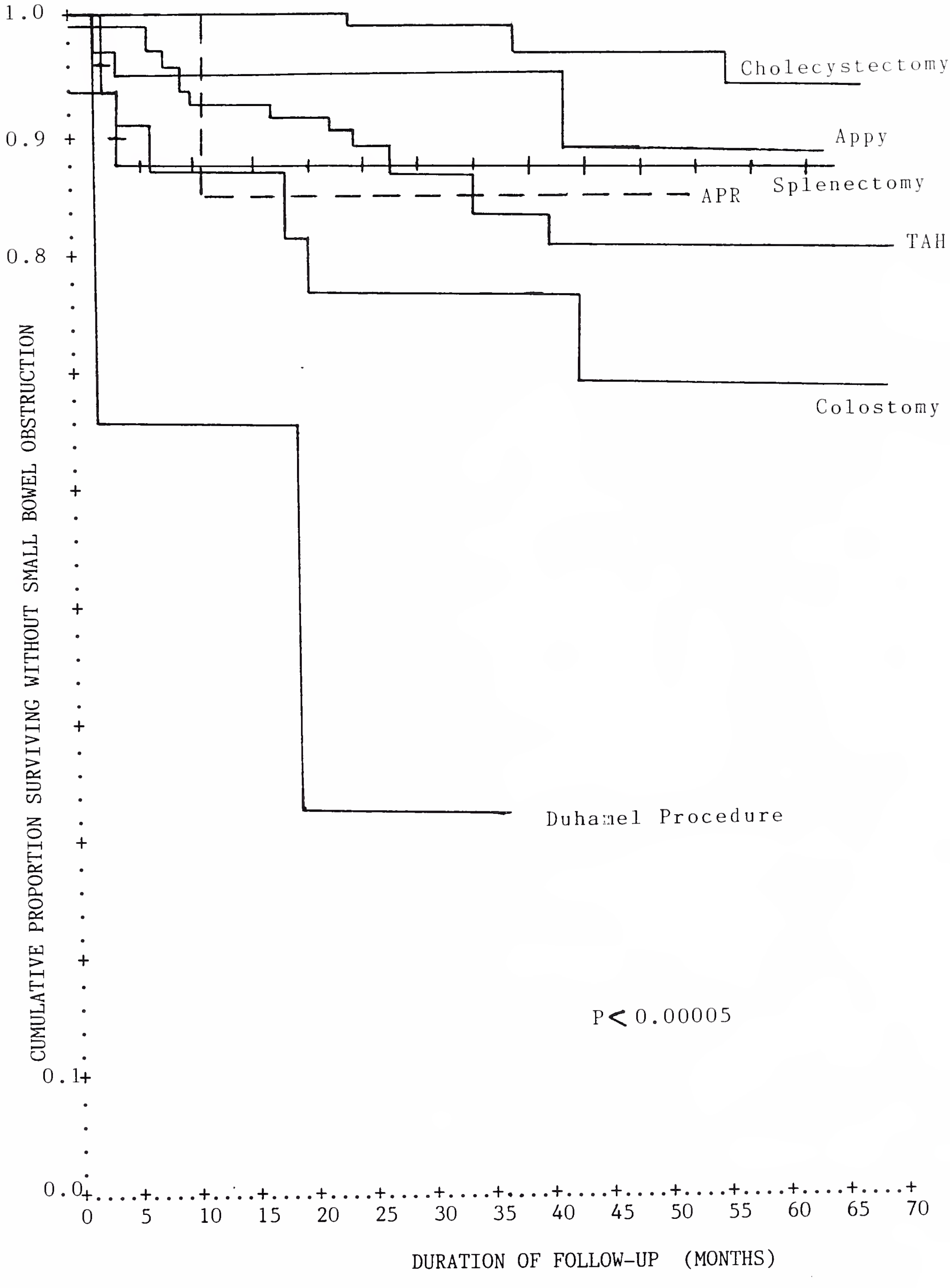

Figure I: Kaplan-Meier analysis of cohort for incidence of SBO-free outcome after various abdominal procedures

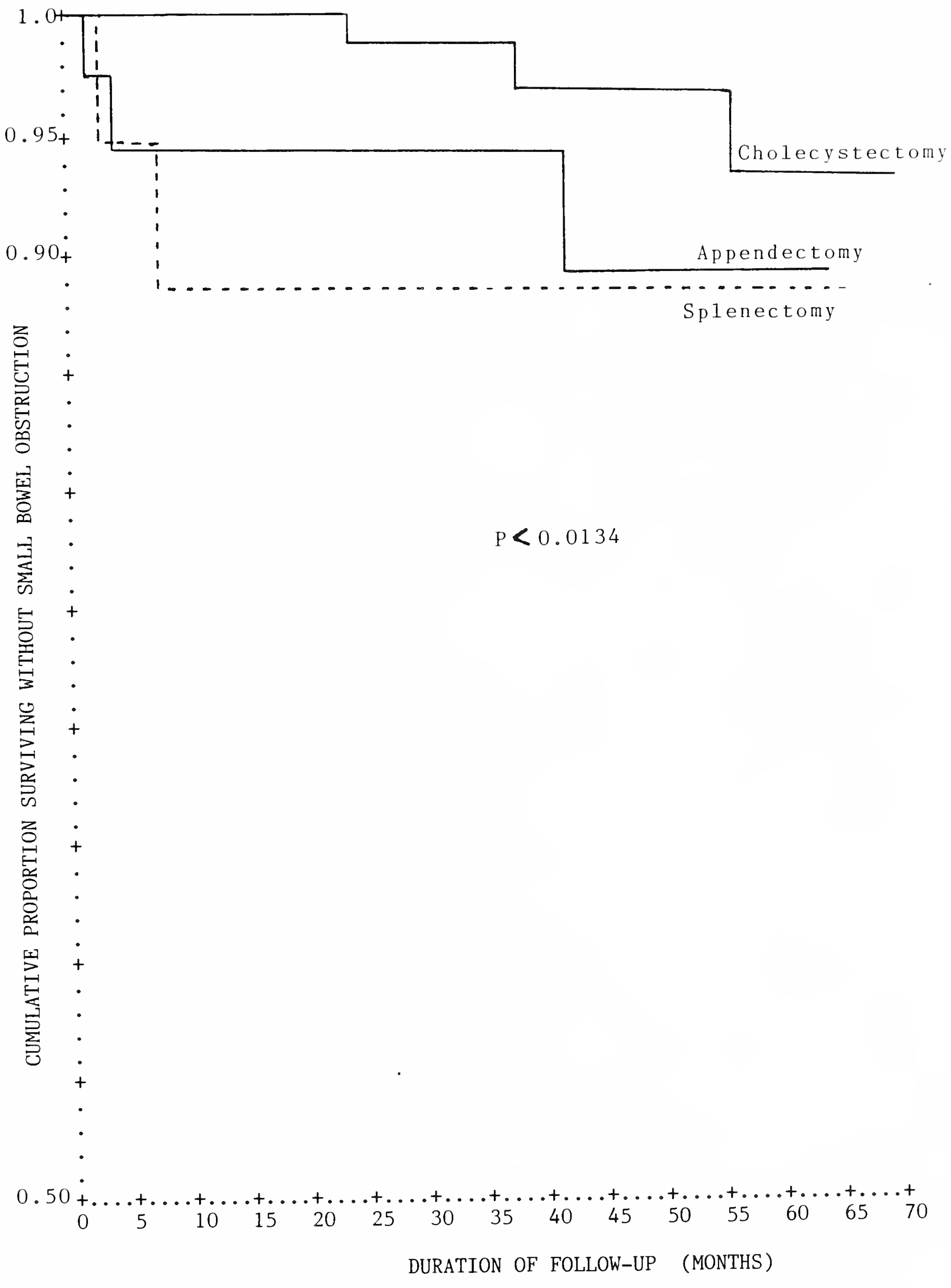

Figure II: Kaplan-Meier product-limit analysis of cohort for incidence of SBO-free outcome after chole, appy and splenectomy

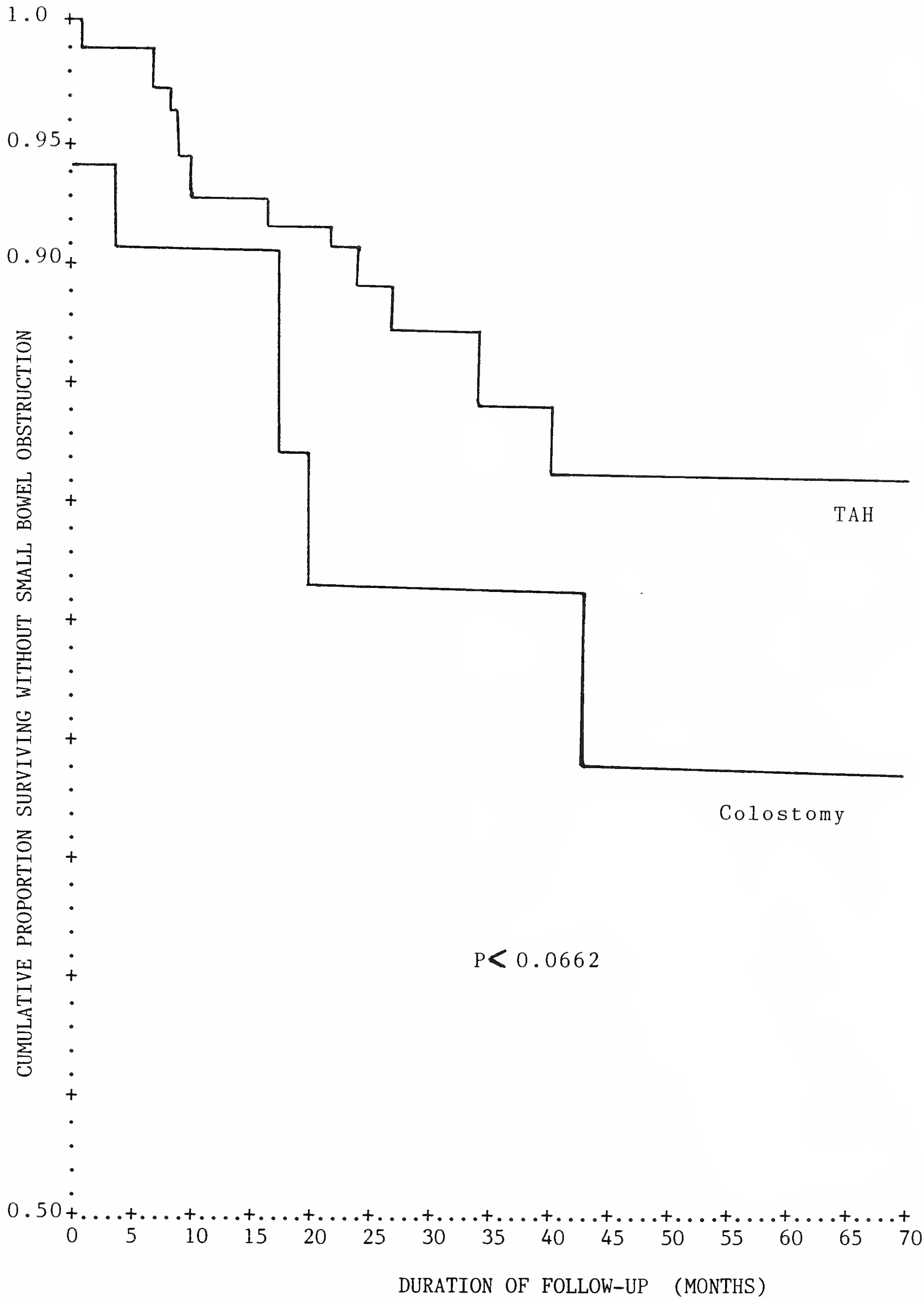

Figure III: Kaplan-Meier product-limit analysis of cohort for incidence of SBO-free outcome after TAH and colostomy

Figure IV: Age Distribution of Post-op Patients with Cancer Presenting with SBO

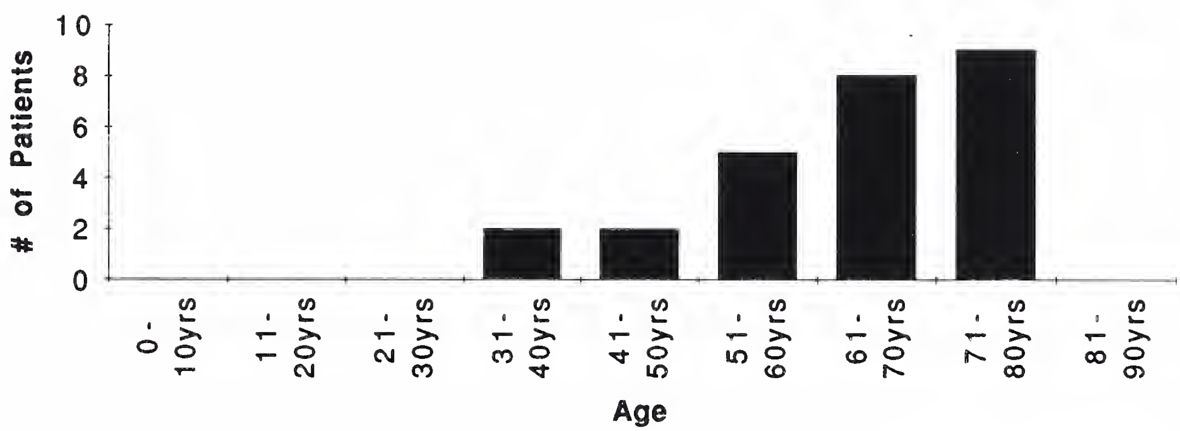

Figure V: Age Distribution of Post-op Patients without Cancer Presenting with SBO

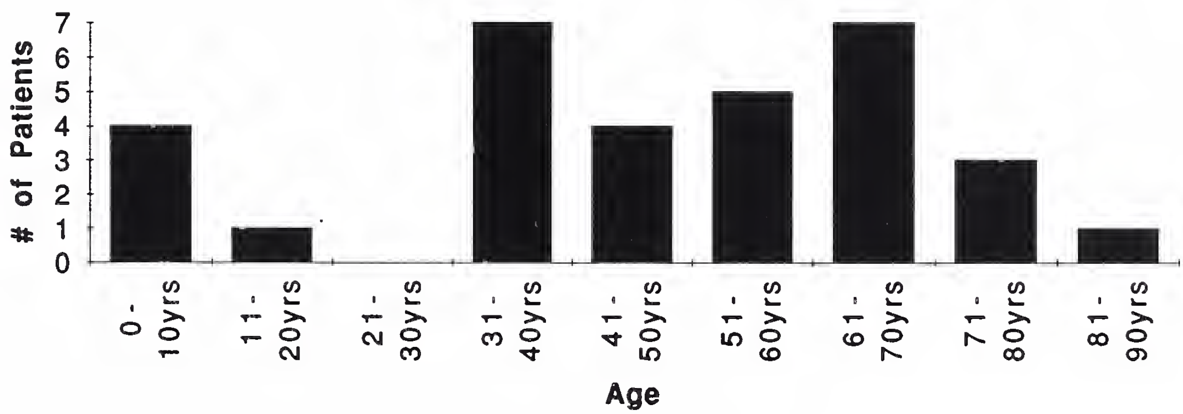

TABLE I

Previous Studies Concerning the Etiology of Intestinal Obstruction

Author	Year	Etiology of Intestinal Obstruction		
		Hernia	Adhesions	Malignancy
Gibson	1888-1898	35%	19%	-
Vick	1925-1930	45%	7%	15%
Eliason	1934-1943	23%	27%	20%
Cantor	1950	8%	56%	-
Waldron	1956	12%	40%	14%
Coletti	1964	7%	91%	-
Laws	1963-1972	8%	69%	10%
Playforth	1970	23%	60%	9%
Stewardson	1967-1976	24%	64%	7%
Chakrabarty	1968-1974 (India)	51%	10%	8%
Bevan	1976-1980	-	40%	7%
Brolin	1976-1980	19%	57%	12%
McEntee	1987	25%	32%	26%

TABLE II

List of Abdominal Procedures which Index a Patient as a Member of the Postoperative, Surgical Cohort

ICD-9 Procedure Code	Procedure Name	Procedure Count In FY86
38.34	AAA w/ Anastomosis	8
38.44	AAA w/ Replacement	38
41.43	Partial Splenectomy	1
41.50	Total Splenectomy	53
42.40	Esophagectomy, NOS	3
42.41	Partial Esophagectomy	1
42.42	Total Esophagectomy	3
43.50	Partial Gastrectomy	1
43.60	Distal Gastrectomy	5
43.70	Billroth II	5
43.89	Partial Gastrectomy NOS	13
43.99	Total Gastrectomy	9
44.00	Vagotomy NOS	14
44.01	Truncal Vagotomy	3
44.02	Highly Selective Vagotomy	1
44.03	Selective Vagotomy NOS	1
44.21	Pyloroplasty, Revision	0
44.22	Pyloroplasty	0
44.29	Pyloroplasty NOS	12
44.39	Gastroenterostomy w/ Bypass	23
44.40	Suture of Peptic Ulcer	2
44.41	Suture of Gastric Ulcer	7
44.42	Suture of Duodenal Ulcer	12
44.49	Suture NOS	0
45.61	Small Bowel Resect - Trauma	0
45.62	Small Bowel Resection NOS	75
45.63	Small Bowel Resection, Total	1
45.72	Cecectomy	10
45.73	Right Hemicolectomy	67
45.74	Resection Transverse Colon	7
45.75	Left Hemicolectomy	23
45.76	Sigmoidectomy	69
45.79	Resection Large Colon NOS	43
45.80	Total Colectomy	8
46.03	Exteriorization Large Bowel	4
46.10	Colostomy	18
46.11	Temporoary Colostomy	3
46.12	Perm. Magnetic Colostomy	0
46.13	Permanent Colostomy NOS	74
46.42	Repair Pericolostomy Hernia	1
46.74	Closure Intestinal Fistula	7
46.76	Closure Large Intest. Fistula	1
46.79	Repair Intestine, other	8
46.80	Correct Instest. Malrotation	2
46.81	Manipulation of Small Bowel	2
46.82	Manipulation of Large Bowel	1
46.85	Manipulation NOS	0
47.00	Appendectomy	179
47.10	Incidental Appendectomy	203

CONTINUED...

TABLE II (continued)

ICD-9 Procedure Code	Procedure Name	Procedure Count in FY86
47.20	Drainage Appendiceal Abscess	2
48.50	AP Resection of Rectum	16
48.62	Ant Resect Rectum, Colostomy	7
48.63	Ant Resect of Rectum	10
48.65	AP Pull Through (Duhamel)	3
50.22	Wedge Hepatectomy	5
50.30	Lobectomy of Liver	9
50.40	Total Hepatectomy	3
50.61	Repair of Liver Laceration	6
50.69	Hepatopexy	1
51.21	Partial Cholecystectomy	1
51.22	Total Cholecystectomy	388
52.53	Subtotal Pancreatectomy	0
52.70	Whipple Procedure	4
53.70	Abd Repair Diaphragm Hernia	11
53.80	Thx Repair Diaphragm Hernia	3
53.90	Repair Dphrgm Hernia, other	4
54.11	Exploratory Laparotomy	424
54.40	Excision Peritoneal Tissue	115
54.50	Lysis of Adhesions	246
54.63	Suture of Lac, Abd Wall	2
54.72	Repair Abd Wall, other	3
54.92	Removal Frgn Bdy Peritoneum	2
54.95	Ladd Operation	3
54.99	Abd Proc for Removal, other	16
65.30	Unil Oophorectomy	140
65.40	Unil. Salpingo-Oophorectomy	112
65.50	Bilat Oophorectomy	5
65.61	Bilat. Salpingo-Oophorectomy	345
66.29	Bilat Endoscopic Tubal Destr	15
66.32	Pomeroy Procedure	160
66.39	Female Sterilization NOS	106
68.30	Subtotal Abd Hysterectomy	3
68.40	Total Abd Hysterectomy	504
68.50	Vaginal Hysterectomy	92
68.60	Radical Abd Hysterectomy	23

TABLE III

Incidence of Small Bowel Obstruction for Various Abdominal Procedures During Follow-Up (FU) Period

Proc.*	Total # of procedures performed in fiscal year 1986	# of pts returning for FU after procedure (%)	Total Months of Follow-Up	# of pts with FU who then develop SBO (%)	Kaplan-Meier Adjusted Incidence Over FU Time	Incidence Density (# Events/1000 Pt-Months of FU)
Duhamel †	3	3 (100.0%)	36	2 (66.7%)	66.7%	52.6
Colostomy	95	34 (35.8%)	69	7 (20.6%)	30.8%	8.3
TAH	504	121 (24.0%)	70	14 (11.6%)	18.2%	4.1
APR †	16	9 (56.3%)	53	1 (11.1%)	14.3%	4.0
Splenect	53	20 (37.7%)	65	2 (10.0%)	11.2%	4.1
Appy	179	41(22.9%)	64	3 (7.3%)	10.7%	2.2
Chole	388	141 (36.3%)	67	3 (2.1%)	6.4%	0.7
Vag Hyst	92	15 (16.3%)	70	0 (0.0%)	0.0%	0.0
Gastroenterost †	23	8 (34.8%)	11	0 (0.0%)	0.0%	0.0

***ICD-9 Codes:**

Appendectomy = 47.0
Colostomy = 46.1x
TAH = 68.4
Vag Hysterectomy = 68.5
Cholecytectomy = 51.22
Splenectomy = 41.5
Gastroenterostomy = 44.39
Duhamel Proc = 48.65
APR = 48.5

† These cohorts had fewer than ten patients each and are not necessarily representative of the general population. For further comment, see Discussion.

TABLE IV

Distribution of Gender in Post-op Patients with Small Bowel Obstruction

Gender	# of patients without Ca	%	# of patients with Ca	%
Males	15	46.9%	6	23.1%
Females	17	53.1%	20	76.9%

p value = 0.061 by chi-square test

TABLE Va

Total Number of Abdominal Procedures Performed on Patients Prior to Cohort Study

Total # of Abdominal Procedures Performed Prior to Cohort Study	Patients without Ca	%	Patients with Ca	%
None	17	53.1%	13	50.0%
Procedure x 1	13	40.6%	13	50.0%
Procedure x 2	2	6.3%	0	0.0%
Procedure x 3	0	0.0%	0	0.0%

TABLE Vb

Total Number of Subsequent Abdominal Procedures Performed on Patients Since Entering Cohort (Excluding Index Procedure)

Total # of Abdominal Procedures Performed since Entering Cohort *	Patients without Ca	%	Patients with Ca	%
None	30	93.8%	20	76.9%
Procedure x 1	2	6.3%	6	23.1%
Procedure x 2	0	0.0%	0	0.0%

* p value = 0.026 by Fisher's Exact Test

TABLE VI

Average Total of Hours in Surgery Per Patient Since Entering Cohort

	Patients without cancer	Patients with cancer
Avg Total Hrs in Surgery per Patient *	2.6	3.5
Total # of Procedures Performed	37	34
Number of Patients	32	26

* $p < 0.0005$ by Cochran's Method

TABLE VII

Treatment of Patients Presenting with Small Bowel Obstruction After Previous Abdominal Surgery at YNHH.

	# of pts immediately to surgery	% of pts immediately to surgery	# of pts Rx'ed w/ long tube successfully	% of pts Rx'ed w/ long tube successfully	# of pts to surg after at least 24h of long tube	% of pts to surg after at least 24h of long tube
Patients More Than 30 Days Post-Op (Delayed SBO). *	10	19.6%	22	43.1%	13	25.5%
Patients Fewer Than 30 Days Post-Op (Early SBO).	4	57.1%	3	42.9%	0	0.0%

* 6 additional patients from this group received tube therapy and were discharged to Hospice in terminal condition.

TABLE VIII

Average Length of Hospital Stay for Postoperative SBO after More Than 30 Days from Surgery

	Pts without cancer	Patients with cancer	p value
Avg length of stay for immediate surgical treatment of SBO.	11.4 days	17.5 days	p value > 0.05 *
Avg duration of medical therapy in those who fail intestinal tube therapy.	6.4 days	13.2 days	p value > 0.05**
Avg total length of stay for those who require surgery after failed tube therapy.	21.3 days	20.0 days	p value > 0.05*
Avg length of stay for those with successful intestinal tube therapy.	4.7 days	7.2 days	p value > 0.05**
Avg length of stay for those who are discharged to Hospice after failed intestinal tube therapy.	-	22.5 days	

* Two sample t test for independent samples with equal variances.

** Two sample t test for independent samples with unequal variances. (Cochran's Method)

Note: P value < 0.005 by Cochran's Method when comparing "Avg length of stay for immediate surgical treatment" to "Avg length of stay for those with successful tube treatment" and "Avg total length of stay for those who require surgery after failed tube therapy" to "Avg length of stay for those with successful tube therapy" in both patients without and with cancer

TABLE IX

Cancer Histology in Patients Presenting with Small Bowel Obstruction and a Past Medical History Remarkable for Surgically Treated Cancer

Cancer Histology	Number of Patients	% of Cancer Patients
Gyn Cancer	13	50.0%
Ovarian	8	30.8%
Uterine	5	19.2%
Colon	10	38.5%
Gastric	2	7.7%
Lymphoma	1	3.8%

TABLE X

Type of Small Bowel Obstruction in Postoperative Patients

Etiology	# of patients without Ca	% without cancer	# of patients with cancer	% with cancer
Previous surgery more than 30 d prior to SBO (Delayed SBO).	25	78.1%	26	100.0%
Previous surgery fewer than 30 d prior to SBO (Early SBO).	7	21.9%	0	0.0%

TABLE XI

Most Recent Abdominal Procedure Performed Before Small Bowel Obstruction in All Patients Fewer Than 30 days Post-op (Early SBO)

Procedure	# of pts without Ca	% without Ca	# of pts with cancer	% with cancer
Colectomy	3	42.9%	0	0.0%
E Lap	3	42.9%	0	0.0%
E Lap	1	14.3%		
E Lap & LOA	2	28.6%		
TAH	1	14.3%	0	0.0%

TABLE XII

Most Recent Abdominal Procedure Performed Before Small Bowel Obstruction in Patients More Than 30 days Post-op (Delayed SBO)

Procedure	# of pts without Ca	% without Ca	# of pts with cancer	% with cancer
Colon Surg	5	20.0%	9	34.6%
Total Colectomy	2	8.0%	3	11.5%
L Colectomy	1	4.0%	0	0.0%
R Colectomy	1	4.0%	1	3.8%
Colostomy	1	4.0%	5	19.2%
TAH	4	16.0%	7	26.9%
Cholecystectomy	3	12.0%	0	0.0%
E Lap	2	8.0%	4	15.4%
E Lap	0	0.0%	2	7.7%
E Lap & LOA	2	8.0%	2	7.7%
Appendectomy	2	8.0%	0	0.0%
Splenectomy	2	8.0%	0	0.0%
Gastrectomy	1	4.0%	2	7.7%

TABLE XIII

Small Bowel Obstruction Secondary to Cancer as Examined in Various Studies

Author	Year	% of SBOs in patients with carcinoma	In-Hospital Mortality among Ca patients presenting with SBO	Total mortality due to Ca
Nemir	1952	19.5%	20.2%	47.2%
Stewardson	1978	7.1%	41.2%	53.8%
Bizer	1981	8.6%	34.3%	44.4%
Brolin	1983	9.7%	35.3%	40.0%
McEntee	1987	26.0%	11.5%	26.9%
Zbar	1991	44.8%	0.0%	0.0%

TABLE XIV

Mortality Rates Among All Patients Presenting with Small Bowel Obstruction in Previous Studies

Author of study	Years of study	Mortality of all patients admitted w/ SBO
North	1905-1922	30.5%
Brill	1922-1928	36.3%
Eliason	1934-1943	11.0%
Nemir	1940-1950	10.0%
Playforth	1970	4.5%

TABLE XV

A Comparison of Studies in the Treatment of Patients Presenting with SBO after Previous Surgery

Author	Year	Study Limits	# of pts immediately to surgery	%	# of pts Rx'ed w/ long tube sucessfully	%	# of pts to surg after at least 24h of long tube	%	# of deaths	Overall mortality
Hofstetter	1981	Post-op SBOs after more than 30d from operation. Excludes cancer patients.	9	17.3%	21	40.4%	22	42.3%	0	0.0%
Zbar	1991	As above.	8	33.3%	9	37.5%	7	29.2%	0	0.0%
Bizer	1981	Post-op SBOs in all-comers within 30d of operation.	1	4.8%	9	42.9%	12	57.1%	1	4.8%
Quatromoni	1981	Post-op SBOs in all-comers within 30d of operation.	0	0.0%	30	73.2%	11	26.8%	1	2.4%
Frykberg	1989	Post-op SBOs in all-comers within 30d of operation.	0	0.0%	11	42.3%	15	57.7%	2	7.7%
Zbar	1991	As above.	4	57.1%	3	42.9%	0	0.0%	0	0.0%

TABLE XVI

Earlier Studies Regarding Types of Most Recent Abdominal Procedures Performed in Patients with Small Bowel Obstruction who are Fewer Than 30 Days Post-Op (Early SBO)

Author	Year	Study Limits	Previous Surgery	% of pts having procedure
Miller	1959	Post-op SBOs while pt still in-house only	Colon Surg Gyn Surg	35.7% 35.7%
Coletti	1964	SBOs within 21 days post-op only	Colon Surg Gyn Surg Gastrectomy	51.1% 15.6% 4.4%
Sykes	1974	Post-op SBOs while pt still in-house only	Colorectal Appendectomy Hysterectomy	46.2% 23.1% 11.5%
Quatromoni	1980	Gyn Surg not included. SBO within 30 days post-op only	Colorectal Appendectomy Liver/Spleen Gastrectomy	26.8% 26.8% 17.1% 14.6%
Frykberg	1989	SBO within 30 days post-op only	Colon Surg Gyn Surg	38.5% 15.4%
Zbar	1991	SBO within 30 days post-op only	Colon Surg E Lap TAH	42.9% 42.9% 14.3%

TABLE XVII

Comparison of Studies Regarding Types of Most Recent Abdominal Procedure Performed in Patients with Small Bowel Obstruction who are More Than 30 Days Post-op (Delayed SBO)

Author	Year	Previous Surgery	% of pts having procedure
Nemir	1952	Pelvic Surg	29.5%
		Appendectomy	18.8%
Miller	1959	Pelvic Surg	45.8%
		Appendectomy	33.3%
		E Lap	8.0%
Raf	1969	Appendectomy	37.8%
		Gyn Surg	27.7%
		Gastric Surg	7.8%
McEntee	1987	Appendectomy	25.0%
		Colonic Resect	25.0%
		Hysterectomy	11.7%
		Cholecystectomy	5.0%
Zbar	1991	Colon Surg	27.5%
		TAH	21.6%
		E Lap	11.8%
		Cholecystectomy	5.9%
		Gastrectomy	5.9%

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